

Theodore Ellenbogen

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Margaret J. Ellenbogen
Margaret J. Ellenbogen

October 23, 1986
Date

Accepted:

John Parascandola
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Introduction

This interview with Theodore Ellenbogen is one of a series of interviews carried out with key persons involved with the passage of the Kefauver-Harris Amendments of 1962 to the Food and Drug Act.

This act comprised the most significant alteration of the Food and Drug Act since the 1930's. In part the amendments tightened pre-market clearance of prescription drugs by adding the requirement that drugs had to be proven effective, as well as safe, for their intended purposes. Among other things the act also attempted to correct advertising abuses, tighten labeling requirements and broaden inspection powers of the Food and Drug Administration.

The passage of the act was preceded by an extensive investigation into the economics of the ethical drug industry under the guidance of Senator Estes Kefauver's Antitrust and Monopoly Subcommittee. Senator Kefauver's main legislative goal had been to reduce prescription drug prices by infusing greater competition into what he felt was a market dominated by a relatively small group of large manufacturers. He intended to do this through a series of regulations the most controversial of which involved alteration of the patent laws as they pertained to prescription drugs. Most of his pricing amendments were deleted from the law before passage. Indeed there probably would have been no legislation enacted at all except for the thalidomide tragedy which spurred Congress to action.

Theodore Ellenbogen, the subject of this interview, was most instrumental in shaping the legislation that was eventually to become the Kefauver-Harris Amendments. As Deputy Chief of the General Counsel's Office of the Department of Health, Education, and Welfare, Mr. Ellenbogen, among many other responsibilities, was the attorney who drafted most of the department's bills dealing with Food, Drug, and Cosmetic legislation. As the man most intimately acquainted

with the HEW's version of the bill, Mr. Ellenbogen can offer much insight into the complexities and difficulties inherent in such legislation, as well as the various transitions the bill went through before its final passage into law.

Mr. Ellenbogen proved to be a most cooperative subject. Not only was he willing to delve into complex subjects in detail, but he also frequently dug back into departmental records to help refresh his memory. The result is over five hours of tapes, recorded at his home in Washington, D.C. in March 1974, which form the basis of the transcript presented below. A word of caution is in order, however. Mr. Ellenbogen, in order to present as accurate an account as possible, rewrote and edited the original transcript to a considerable extent. The transcript here presented will therefore differ somewhat in many places from the original tapes. The changes were beneficial in clarifying and further amplifying the difficult subject matter under consideration in this interview.

I wish to thank Mr. Ellenbogen for the great care and interest that he took in this project.

Richard E. McFadyen, Ph.D.
History Department
University of North Carolina
at Greensboro

M: Today is March the 1st. My name is Richard McFadyen of the History Department of the University of North Carolina at Greensboro. This is an interview with Mr. Theodore Ellenbogen--am I pronouncing your name right? (E: Yes, you are.) Good. To get us started, I'd like to ask you just to give me a little biographical background in terms of education and how you got into your position in HEW at the time of the Kefauver legislation.

E: You mean how I got employed by HEW? Or how I got into the handling of this particular bill?

M: Well, how you got employed by HEW (E: Ohh). Just very briefly--background.

E: Well, well. Of course I'm a member of the Bar. I was admitted to the Pennsylvania Bar in 1929--I suppose before you were born? (M: Yes. I'm a few--) (chuckle) (In 1937, I also was admitted to the Bar of the U.S. Supreme Court, and in 1951 or 1952 the District of Columbia Bar.) In the summer of 1930--after less than a year of private practice--I became a member of the editorial staff of the West Publishing Company--that's the largest legal publishing house in the country--for about six years, until November 1936, when I was employed by the Social Security Board as an attorney in Washington. I was with the Social Security Board, in the General Counsel's office, in several capacities until the board became a part of the newly established Federal Security Agency in 1939, to whose General Counsel's Office we lawyers were transferred. I might say that initially, when I joined the Social Security Board, I worked on legislation, research, and business law. Later, both while under the Board and in the Federal Security Agency, I worked on various subjects, including unemployment compensation and litigation matters. Then I was Principal Attorney in the Old Age and Survivors Insurance Division

of the General Counsel's Office, a position equivalent to what is now called Deputy Assistant General Counsel. Then from 1945 until late in 1947 I was in the military government for Germany--the U.S. Military Government for Germany. When I returned, I rejoined the General Counsel's Office of the Federal Security Agency, this time as a member of the legal staff of its Legislative Division. The FSA later became the Department of Health, Education, and Welfare in 1953. But I remained in that division, being promoted from time to time, until my retirement in 1969. While I had handled many other matters, I had for a number of years been drafting any legislation that the administration--the Department--wanted to submit under the Food, Drug, and Cosmetic Act--or in that field, including the Food Additive Amendments of 1958 and the Color Additive Amendments of 1960. And so, when the so-called Kefauver-Harris amendments and so forth came up--that was naturally entrusted to me to handle for that division, especially since I had been drafting legislation on that very same subject. I was then Deputy Chief of the division. I subsequently became Assistant General Counsel in charge of the division.

M: Right. Did--did you by any chance have anything to do with the original drafting of the 1938 Food and Drug Law?

E: No. I did not. At that time, the law then in force, the Food and Drugs Act of 1906, was administered by the Secretary of Agriculture, and so was the 1938 Act upon its enactment. (M: uh-huh) And that was not transferred to the Federal Security Agency until--I have forgotten whether it was a part of the original Federal Security Agency reorganization plan of 1939 or 1940 or was added in. (M: I thought that might be an interesting link--that I hadn't thought about.) No, I was not.

M: Let's stop a minute.

E: I should say, however, that I have--I have the legislative history, in book form, of the original Food, Drug, and Cosmetic Act by Charles Wesley Dunn, published in 1938, and I have delved into that extensively in connection with reports on proposed legislation that I handled and drafting legislation.

M: One of my predecessors at Emory University has published a book called "Food and Drug Legislation during the New Deal." (E: Oh?) He did it the same--somewhat similar to what I'm doing.

E: I see. Well, the one I have is actually verbatim legislative history. (M: Right, right--the raw material.) I have it upstairs.

M: Okay. Well, this--this provides us a background for getting into the Kefauver end of it. Um. Were--were you a--when did you first become aware of--of the Kefauver bill?

E: Well. What happened--let--could I sort of rephrase this? (M: Please.) We, in the Department of HEW had been contemplating proposals in the new-drug field--and antibiotic field--and other amendments--long before Kefauver had proposed his legislation. And I actually drafted--but I do not remember whether that was in 1961 or 1962--an omnibus bill that would be--would have been called the "Food, Drug, and Cosmetic Amendments of 196--"--whatever it was--that would have not only included all the amendments that we considered at that time necessary or desirable in the drug field, but also in relation to food and cosmetics and therepeutic devices. And, in the case of factory inspection, a liberalization across the board. And--um--in the course of the hearings that Kefauver was conducting--he was conducting an investigation into, isn't it called "price administration?" (M: Administered prices.) Administered prices--and I think he started with the steel industry (M: right). And then he

went into the so-called ethical or prescription drug industry. And, in the course of hearings on that aspect, he invited people from HEW, particularly, I think, Mr. Larrick who was then Commissioner of Food and Drugs, and the Secretary of HEW, who was then Secretary Flemming, I think. (M: That's right.) And in the--in the course of those hearings--and I have not refreshed my recollection on those for many years--I have not had time to do it for this--those people advanced ideas that later he--Kefauver--decided to incorporate in his bill, including new-drug efficacy (M: um-hum) as a condition of clearance for the market of those drugs, and including as well the certification of all antibiotics--batches of antibiotics--not only those five groups and their derivatives that were then required to be certified. Actually, the Secretary, and Mr. Larrick, should not really, at that time, have aired these proposals before Kefauver because there was a general rule that witnesses on behalf of the Department--and this would be true, presumably, of any government agency--should not, in testifying before Congressional committees, make legislative proposals until those proposals had gone through a regular clearance process within the Administration. (M: Right.) And then we would have come up with our own proposals and, in fact, at that time that is what we were thinking about.

M: All right. Now. This--this is a very interesting point. Now--

E: I don't know whether this has come out in your interviews or not.

M: Yes, it has. Except I'm still not clear on it. It seemed to me in going through the written records, that it seemed that Kefauver got FDA moving once again. In other words, in terms of--of advocating new legislation. And that it seems that it's true that FDA sent its own bill to Congress in July.

E: But not its bill--that was the Department's bill.

M: Well--the Department--the FDA/HEW bill--

E: Yeah. But it's HEW's bill, not FDA's. Now that may seem the same to you, and it does to many people in Congress and I see it all the time in reading reports and so on. But it was only the Department that could make a legislative proposal officially. (M: uh-huh) Yes, of course FDA would come up with proposals to the Secretary, though there were things that we got into our bill that did not emanate from FDA.

M: Right. Who would initiate--in other words, what department or what individual was responsible for seeing that new legislative proposals are coming forth?

E: Well. Of course it differed from one Presidential administration to another. But at that time and since, basically, prior to the beginning of each Congress, the Department would develop a legislative program for submission to Congress, to be cleared through the Bureau of the Budget at that time and the White House.

M: Okay. May I interrupt? But the point I'm trying to make is--true, the Department presented its omnibus bill in 1960--(E: Was it 1960?) Yes. I--I had--that was the--in 1960. (E: I see.) Ah (E: But that never went to the Hill.) No. Uh--why, why wasn't it presented in 1959? Or 1958?

E: Oh. Well, some of those--uh--some of the things in it might well have been in the form of separate bills. But I remember the question of an omnibus bill. It was a tactical--a strategic question. It was semi-political as to whether we should have separate proposals or have one proposal, and there was discussion back and forth and the powers-that-be decided 'Let's have an omnibus bill.' Actually, I believe, that decision was reached in the Kennedy Administration. I myself had some question about that because it's just too big a thing (M: um-huh) although--well--although in nineteen hundred and thirty-eight,

the so-called original Federal Food, Drug and Cosmetic Act which was a successor to the Pure Food and Drugs Act of 1906 (M: True. It wasn't the original.) was an omnibus bill. But that took three Congresses to get enacted. (M: Right.) Three Congresses! (M: Right.) Because it was such a big and largely controversial thing. And at that time, in 1938, cosmetics were covered for the first time. And the new-drug section came in almost accidentally. Do you remember that?

M: The Sulfanilamide?

E: Yes. The Elixir Sulfanilamide episode.

M: Right.

E: So it seemed to me--I myself would have preferred not to have an omnibus bill because it's just too big a subject. (M: Right.) But the powers-that-be decided to have an omnibus bill. So that's what we prepared. Now, actually it never went to Congress in that form because--probably because--of the end run by Kefauver. And--shall I go on?

M: Well, let me--I'm (E: Yeah.) still working on this point. What I'm trying to do is to establish 'Is there or is there not a link between Kefauver's investigation--Kefauver's bringing a spotlight on drug problems--and the fact that in 1960 FDA comes up with its omnibus bill.'

E: No--

M: Seems to me that there is--

E: No. No sir. No. On the contrary. (small chuckle) We were thinking of these things--to do ourselves--and it just was coincidental that Kefauver had a series--was contemplating a project--a series of investigations on

"administered prices" in various industries. Well, after the steel industry they started on the drug industry, and his approach--and of course that of his principal assistant, Dr. Blair, who was an economist--(M: Right.) And they were naturally groping how to stimulate competition in the drug industry in the so-called ethical drug industry--that's the only one they were investigating at the time. So you can call it--if you like, yes, a link in the sense that our people were called and their thinking was aired before the Kefauver subcommittee and taken up by Kefauver. But not in the sense that we got the idea from Kefauver to make these proposals. However, I'd like to make a couple of exceptions to that. I think--and I may be mistaken in my recollection--but I think very likely the idea that where labelling--or the label--had on it both the brand name of the manufacturer and, as required the "common or usual name"--popularly known as 'generic' name (M: Right.) which is somewhat of a misnomer--it should be required that the generic name be at least in the same size, that was Kefauver's idea. And later it became law as 'at least half the size' of the other. I think that probably emanated from Kefauver's thought. I don't think--at least I do not recollect that we had that idea in the first place.

M: Yes. I think that was his idea.

E: Secondly, as to the standardization of generic names. I doubt very much that that originated with us. I think it originated with Kefauver, except that his bill, in my opinion, was poorly drafted and resulted in a poor--not as bad as his--but still a poor draft at the end. Now we'll come to that later. In fact, on that one proposal, the Food and Drug Administration, which first wrote a draft HEW report on the bill which I rewrote--was very cool. They said, in effect, 'Well, if it's law, we'll do our best to administer it.' But I felt that there was a lot to it. I looked into the hearings before Kefauver and

found Dr. Miller's testimony on some of it, and I called Dr. Miller long distance and discussed it with him, and he sent me an article on it and so forth. It's in the file. And I--I--the HEW report that I wrote was quite favorable, in principle, to that provision--except that I felt we should have stand-by authority rather than, as Kefauver had phrased it, be required to--uh--(M: have primary authority) primary--not only authority, but duty to investigate and coin all generic names. Thirdly, his proposal for Federal licensing of drug manufacturers was not HEW's idea. But, basically, he was really cutting across our paths, as it were, and--uh--this may come out later. I think he did his very best to thwart and prevent the submission of an Administration bill. (M: Yes.) In fact, in form, he succeeded.

M: In fact, what?

E: In form.

M: 'In form.'

E: Our bill was never formally submitted as an Administration bill at that time, although we did informally send up, as I recall, a drug and factory inspection bill and a separate bill covering everything else on the House side. Only the "everything else" bill was sent to the Senate side, presumably as the result of negotiations between Kefauver and the Department and/or White House.

M: Well, again, I'm still wondering--

E: And, incidentally, you may notice that in our--that what we sent to the House--but we'll come back to it. We included a whole part on barbiturates and amphetamines and so forth. Which was one of the things we had been thinking about. But that didn't fit into Kefauver's scheme, you know. But

we included it.

M: Do you think the changing of Administration had anything to do with the-- well, in 1960, this is, you informed Kennedy--

E: Well. Thinking started in the preceding--in the Eisenhower Administration. (M: Right.) And the testimony that I mentioned before Kefauver's Antitrust and Monopoly Subcommittee (M: Right.)--that started in that Administration. Secretary Flemming testified (M: right). So we did start at that time. But the--the way Kefauver was handled--and the way the strategy evolved, I surmise might have been quite different if a Republican administration had continued in office.

M: Could you elaborate on that a bit?

E: Yes. Because Kefauver was by and large, an adherent of the philosophy of the Kennedy Administration and he had--naturally, being a Democrat--a better entree at the White House than he would have had with a Republican President. And he, you see, did everything (chuckle) he could at the White House to prevent and Administration bill from going up!

M: It didn't seem to really help him too--(chuckle)--too much as the story develops.

E: Well--it helped him a--well, I think it helped him considerably. We'll come to that, I think.

M: It--it helped him--well, okay--we will come to that.

E: Maybe. I don't know--

M: Yeah.

E: If not, we can--

M: All right. Let me just stop a minute.

Slight break in recording

All right. I wanted to ask you a few questions about this original departmental bill. We've already talked about it a bit. (E: Yes sir.) As I indica--I have the impression that the bill was rather hurriedly put together.

E: Meaning what? (M: Meaning--) In order to meet some other situation?

M: Yes, and I thought the other situation was--was Kefauver's presence. In other words, Kefauver was imminently going to present a bill so FD--uh--the Department said, 'Well, we'd better beat him to the punch!' Am I wrong?

E: I think you--when was this omnibus bill? This was in '61 wasn't it? Oh, you say 1960?

M: Let's stop again

Break

E: I--before, you inquired how 'the Department develops your legislative proposal' and I started telling you that every year,--well in advance of a new session of the Congress--both from the standpoint of preparing for the new budget insofar as it involves new legislation and for developing new legislation, the Assistant Secretary for Legislation (at least that was so in my time) would send around an invitation to all the--to all of the constituent operating agencies of the Department, and certain other people, perhaps, as to any legislative proposals that they thought the Department should make. And give them a deadline. And then the Department would review those. We, as the Legislation Division of the General Counsel's office, would be involved in reviewing those and we might have ideas of our own, too. And then there would be meetings with those people and eventually the Assistant Secretary might then

propose a program to the Secretary. Nowadays other people will come in-- the Assistant Secretary for Planning and Evaluation, the Assistant Secretary for Health, and so forth. In those days, though, it was much simpler. You had the Assistant Secretary for Legislation who, under the Eisenhower Administration, was, first Rodney Perkins and then Elliot Richardson, and then when the Kennedy Administration came in it was Wilbur Cohen who later became Undersecretary and then Secretary. And this is how a legislative proposal was evolved. And normally, at that point, we didn't take the time to draft legislation actually, but we would--the proposal would have basic specifications as to what we wanted to do. If there was--if it was repeating a proposal made in a prior Congress, we would say so and refer to it. And our proposal would go to the Budget Bureau and later on, unless the proposal was knocked down before, we would draft a bill and send it to the Budget Bureau or White House for clearance. This is why I'm so emphatic in saying that we are not--that there is no such thing as a legislative proposal sent to Congress by the FDA.

M: Okay. I understand that now.

E: Sure. Shall we stop?

M: Yes. Yes, let's stop and you can read a couple of paragraphs there and then we'll come back.

Break in Recording

E: Where shall I start now?

M: Um. Well, Mr. Ellenbogen is responding to some comments in my doctoral dissertation referring to who--what's the act? The--

E: You mean the "Factory Inspection and Drug Amendments of 1960"?

M: Right. Right.

E: Bill.

M: Right.

E: Well, you say that 'the FDA'--you say before that, 'the FDA began a crash program to pull together a proposal for amendments to carry out the goals outlined by Larrick and Flemming before the Kefauver Committee. But before the FDA could send its recommendations to Congress, Kefauver introduced his first drug bill--S3677--on June 15th, 1960. Nevertheless, the FDA pushed ahead with plans for its own bill.' Well, I wish you had reminded me about that other bill because I--I can't remember--and I don't think we ever reported on it. Do you? No?

M: Uh--I don't--I believe it was--scrapped.

E: But this--uh--it may be that there was an effort to speed up what we would have done ourselves. But certain it is that we would have come up with legislation of our own on these very matters that were outlined by Larrick and Flemming before the Kefauver Committee. (M: hmmm) The one thing that required further clearance within the administration was the question of requiring that new-drug clearance for the market be conditioned on a showing not only of safety but also of efficacy. Because that raised very deep and important questions of policy and required clearance within the administration--not only within the Department. The Budget Bureau would have wanted to consult, for its views, the Commerce Department, for example, and others. So that, I hope you do not have the impression that the Department would not have come forward with these very proposals unless it were for the Kefauver hearings.

M: Well, I'm afraid that--that is the impression I have, I--

E: Well I don't think there's any sound basis for that.

M: Well--ah--not that the Department wouldn't have come up with them, but that Kefauver certainly hurried up the process.

E: Well, it may be. I wish you had let me see this before so I would have tried to refresh my recollection on it and gotten those files in the Department to look at. I have no recollection of this going up before, but--uh--it may well be that--uh--that happened. If--if it did go up without Budget Bureau clearance, then it would--it could not have gone up as a legislative proposal of the Department. Maybe it was sent up for information to--oh! Wait a minute! To whom was it sent, anyway? It was--

M: Well, somewhere in--

E: To whom was it sent? It doesn't say--it says by whom it was introduced, but not to whom it--to whom our draft bill was sent.

M: Right. Well, somewhere in--in my comment--uh--I reflect on either a memo you wrote or someone else wrote that--

E: There's a--in a footnote--a

M: That you wrote the Budget office that HEW had done this as a technical--a

E: Well, maybe that's what it was--

M: That's--but the memo indicated that it wasn't that.

E: My memo?

M: Yes.

E: My memo to John Harvey?

M: Umm. I--I don't recall--

E: It says here in your opus 'Due to the speed with which the bill was introduced, it had not received the bureau's clearance when it came before Congress.' And then you refer to my memo in the footnote.

M: Do you--do you see my comment somewhere that the--

E: In the text you say 'As late as the day before the introduction of the bill, the Bureau of the Budget did not realize that the bill was not simply a drafting service for the Kefauver Committee, but was an FDA proposal that should be sent to the proper committees in Congress for serious consideration.' Well, I suspect it never was formally sent--you don't know to whom--it doesn't say here from whom the letter was that sent it up--was it sent up by letter? It just says here FDA sent--

M: I believe it was--

E: It doesn't say from whom the letter--was it from the FDA?

M: I--I don't recall right now.

E: If it was from the FDA that in itself would indicate that it wasn't a departmental proposal. Uh--I--

M: What--what--

E: I wish that--I wish I could see that letter.

(Subsequent to this interview, copies of that letter and the memoranda referred to were furnished to Mr. Ellenbogen and he added the following note to the interview:)

The letter, dated 7/1/60, was sent by Secretary Flemming to the Speaker with a draft bill ("Factory Inspection and Drug Amendments of 1960") containing amendments to the FD&C Act to (1) broaden the scope of factory inspection authority,

(2) require record keeping and reports as to clinical experience and other information obtained by manufacturers that would indicate adverse reactions on "new drugs", (3) deem adulterated any drug not prepared or packed under adequate manufacturing controls, and (4) require batch-by-batch certification of all antibiotics. The letter referred, for an explanation of the need for the amendments, to the Secretary's enclosed testimony of 6/3/60 before Senator Kefauver's Antitrust and Monopoly Subcommittee and stated that the Secretary had at that time indicated that the Department would submit the amendments formally to Congress. The letter stated that because of "time limitations" the Budget Bureau was unable to advise, at that time, as to the Administration position on the proposed legislation. These amendments, although not in bill form, had been transmitted by the Secretary to the Budget Bureau on 6/23/60--together with the testimony--with a request for advice as soon as possible in "view of the lateness of the session." It stated also that the proposal on "new drug" efficacy was not included but that he expected to make a decision on it within a few days. A briefing memo from the General Counsel to the Secretary with respect to the transmittal to the Budget Bureau, and a memorandum of 6/29/60 from Mr. Ellenbogen to the Deputy Commissioner (Mr. John Harvey), both indicated that Secretary Flemming was anxious to submit the amendments to Congress without delay and did not wish to hold them up pending completion of the efficacy amendments which would take a few days. A later memorandum from Mr. Ellenbogen to Mr. Harvey referred to the bill as having been submitted on a "'crash' basis." The letters and memoranda referred to in this note, as well as the draft bill itself, were prepared by Mr. Ellenbogen.

M: Am I completely wrong that Kefauver hurried up the process?

E: There's no question that Kefauver hurried up--oh--you mean hurried up our process?

M: Yes, hurried up your process.

E: Well (chuckle) (M: chuckle) I don't know whether you're right or wrong on this particular one. It could be. Secretary Flemming had a way of doing things, frequently,--that were not--according to the rules. You know. And he might say things publicly--or do things--and then it would be a fait accompli for the Budget Bureau. In your thesis you say, 'The trade press suggested that Flemming's call for tightening of drug regulations was taken with a grain of salt by many FDA staff personnel who viewed the Secretary's statements as something cooked-up in the front office to meet a political situation. But by the end of the week, Flemming had gotten his message across that he meant what he had said. Flemming let it be known that he wanted action on his various recommendations within 60 to 90 days.' But I don't know what that means. You notice that it says here, and this is no doubt correct, that, 'Although Flemming's major recommendations did not'--that's before the Kefauver Committee--'did not call for the power of determining the efficacy of a new drug,'--and I might say that this was because he did not feel free to do so--'Yet in the general discussion that followed his statement, Flemming pointed out that Commissioner Larrick's statement called for inclusion of the efficacy provision.' So this was a round-about way of getting before the public the idea that we fully--that there should be such a requirement but he wasn't free to do--to make that proposal at that time.

M: Yes. And what it also suggests to me is that the thing had not been completely crystallized and it was in the process of being crystallized.

E: Well, we had not cleared it within the Administration, for one thing.

M: Right.

E: And I hadn't drafted anything on it--yet--I believe, at that time--on efficacy.

M: Right.

E: I think on some of the other things we had no doubt drafted it repeatedly, and for some of the things you say that might have been done hurriedly I think they were done deliberately in the sense that they were not, should I say....

M: Well, I don't mean here to imply they were sloppy.

E: Sloppy!

M: No. I'm just trying to get to is the cause....

E: I venture that what was sent up probably was something that had already been drafted and it's very important for me to know and I can't tell from here how it went up. Whether there was a letter from the FDA as you say-- you say it was transmitted by the FDA which would not be a regular office.

M: I expect I--that's a misnomer.

E: I suspect that they somehow got it up there before it was released--handed it to the Congressman and introduced by them.

M: Well, we'll just have to check that point--when we--

E: I don't know. I mean--I think if I were in the file I might be able to tell.

M: Right. Well, we can check that point.* Okay. Let's move on just a little bit. What kind of response does the Department have to Kefauver's bill? To S.1552?

E: What do you mean--'What kind of response?'

M: What was the consensus on S. 1552?

E: Well. Let me first say--I think there was and I don't have any objective written evidence to that effect--but I think there was resentment that--he sort

* See note on page 14, ante.

of took our proposals and ran with them to get ahead of us, you know. But worse than that, what happened was he was moving heaven and earth to prevent the submission of an Administration bill to Congress--which we had intended all along, you see. (M: um-huh) And I suppose that after it had been decided to have an omnibus bill, the decision to not do that was due, I think--although I have no direct evidence to that effect--to Kefauver's moving heaven and earth that there be none. There had been a consumer protection message by President Kennedy (M: Right.) in the spring of 1961--no, '62--(M: '62, March '62) 1962 which gave the highlights of our proposal plus--the proposal on drug advertising for amendment to the Federal Trade Commission Act. (M: Right.) You know. And at that time we endorsed that proposal and--uh--am I getting ahead of something here? Oh--you want to know about the feeling--. But now, before Kefauver introduced that bill, we had visits--the first time, I think, by Mr. Flurry, who was counsel to the subcommittee. I think at another time Dr. Blair came down. And Mr. Fensterwald, I think, came down, too. And we met each time, I think, in the office of the Commissioner of Food and Drugs--or some other office--it was in the Food & Drug Administration offices. He had gone to them, being under the same impression, as a lot of people are, that they call the tune.

M: Who--who was in these meetings?

E: Well, I was at the meeting and, I think, Billy Goodrich may have been at the meeting--I know he was then Assistant General Counsel of HEW for Food and Drugs. And I was handling Food and Drug matters for the Legislation Division at that level--not limited to any constituent of the department. And I suppose Mr. Rankin was there but I can't remember for sure. There were some people from Food and Drug and he must have been there. Whether the Commissioner was there, I do not recall. But we went over the draft bill they'd presented at that time and pointed out certain things that called for improvement--also

pointed out that some things had bugs in them--or would not help--and so forth. And I sent up--later on, I think--a draft to Mr. Flurry--it was next year, I think--trying to correct some of the things he had--not correct, but improve. This was particularly on drug names and labelling. But there was very little, if any, reaction from them in the sense of taking those suggestions and improving their bill. I think they were just--maybe they thought they knew better how to draft. One aspect, incidentally, of their draft was bad tactically and technically, I thought. They went through the Food and Drug Act in numerical order of the sections there and amended them in that order, so that there would be unrelated amendments following one another, whereas, the way I draft, I always try to keep a particular subject in one place even though sections of the Act would thus have to be pulled in from various parts of the Act to be amended. Dr. Blair, incidentally, is a very able and brilliant person, but was, at that time, at least--extremely arrogant. He could be very, very rude. Later though, after a blow-up just before the House-Senate conference on the Kefauver bill, I think he finally realized that I was no enemy of his, that I really had the good of the country at heart and I was trying to get things through that were sound, and from then on he was very nice to me.

M: Well--uh--Jerry Sonosky has talked about this point. Not so much in terms of Blair, but with Kefauver. He says that--

E: Well, Kefauver was not rude, but he was a very stubborn, very tenacious person--like a dog with a bone. (M: Um-huh) He--he just wouldn't let go of it. But an attractive person, you know. (M: Um-huh.) And no doubt sincere, but the fact that he had Presidential ambitions, I think, no doubt entered into his psychology heavily there.

M: Do you think Kefauver was--was too tenacious? I mean he didn't--he didn't

know when to compromise?

E: Well, this is hard to say. I think Blair was egging him on. And it's very interesting that on the Senate side, after the first phase of negotiations, after the so-called "secret meetings," called by Eastland, to which he had not invited Kefauver even though we asked him to do so, Kefauver just blew up when he was suddenly confronted--at an Executive session at which I was present and so was Jerry--

M: Yes--but we are getting ahead of this game a little bit. (E: Oh.)
But go ahead and finish what you want to--

E: Well, he was suddenly confronted by this and very much upset and then--after a point of order when 12 o'clock noon struck (chuckle)--he rushed to the Senate floor and lambasted the Committee and I don't know whom else. But, in the second phase, when we had the new negotiations--he was drawn into the negotiations and Blair was the one who really attended for him. Well, Kefauver was greatly pleased and he--I noticed this in looking at the debate recently again--he kept on commending all the members of the Committee and how cooperative they were, and so forth. And I--completely--that's--(makes a flip-over gesture with hand).

M: (chuckle) That's interesting!

E: Even though he still had certain things that he pursued. (M: Right.)
Which is perfectly all right.

M: Um. Could we go back to--uh--comments on the original Kefauver bill? You've already made some comments on--as to the weaknesses of that bill. I wonder if you could elaborate on that.

E: Well--

M: Apart from your--

E: Well, I think the best elaboration would be the report that we sent to Congress--on the bill as introduced.

M: All right. All right. This would be a good place 'cause you were very instrumental in writing that report.

E: Well, I really wrote this report--except--and I can tell you what was changed after my first draft. Our Division was responsible for the development of so-called "reports" of the Department to Congress on bills. Committees would ask the Secretary for his views, and the statement of views in writing to a committee was called a "report." (M: Yes.) And in addition to drafting our bills on food and drug legislation and certain other bills I was primarily responsible for developing such "reports" in our division. Our practice, though, was--we couldn't possibly in the first instance do this ourselves--that when we got a request for such a report we would routinely send it to the interested operating agency or agencies. If we could pin responsibility, in the first instance, on one of the operating agencies, we would ask it to prepare a proposed report and send it to us--preferably in final form. And if we could bring ourselves to pass it we would. If two or more agencies were more or less equally concerned, we asked for comment or information from each and we would then work on a report. Now, not infrequently, we couldn't pass what the agency sent up. We would have to rewrite it, or revise it in part. This was eminently true in the case of the Kefauver bill report, which we had asked FDA to prepare. I wish I had made a copy of their draft that's in the file. And it just, in my opinion, was not adequate--ah--to send up the line for approval by the Secretary and then the Budget Bureau.

M: Would you care to say who wrote it?

E: Well--I don't know for sure who wrote it. And incidentally, this particular one was sent to us in draft, I think, because what I recently saw in the file was a draft. We never got a final one, I think. (M: hmm) And this was a subject--though first of all, they didn't have a competence in the patent field, for example, really. But, secondly, the tone of it was not appropriate, I thought. Some things they didn't go into, or at least not adequately in my judgment. On the patent provisions, well, they frankly said, as they should have, that we really did not have competence in that field, but they said, that if it were enacted, we would do our best to administer it. Now, I'm not sure but I think that, at that time or later, they did point out some of the problems that would arise if the patent provision relating to drug modifications were enacted in its then form. And some of those examples I included in the final report. On the provision of standardization of names, they, I think, said not much more than that if it were enacted the Department would do its best to administer it. I may be mistaken in my recollection on that exactly--but not much more. They were cool on that, and I might say that the provision I'd put into our own bill--which later became the Harris Bill, but not as enacted, and I'll get to that later--on standardization of names, uh, I was responsible for--as a policy matter--of getting that in because I was--I felt that there was something to it. And this idea, I think, was a contribution by Kefauver. And also--

M: That comes through in the written record. I've given you credit for--for fighting for that.

E: Is it in the written--?

M: I believe--I believe it is.

E: I see.

M: That's interesting for you to comment on it.

E: And I believe, as I said before, I think also that the idea of the size and prominence, on labels and labelling, of the so-called generic name of drugs probably stems from Kefauver. Although I then, in pursuing it, found that in biological drugs for humans, we already not only were requiring prominence, but priority in position on the label, for the nonproprietary name.

M: Priority?

E: Priority over the other name. For the name that--that we gave--when I say "we," that was the Division of Biologic Standards in the NIH (National Institutes of Health), since transferred to the FDA. That Division itself, gave or coined names. They are the ones. (M: Ohh!) Yes. So the idea was not new. But I do think the idea stems from Kefauver for this particular legislation. I could be mistaken in that recollection.

Now, certain other provisions sprung from rather a lack of experience, and we suggested to Kefauver's people, when they came to us, that there was no point in those changes--that our regulations were adequate for the purpose. This was true, for instance, of the bill's requirement about sending every physician in the country the whole text of what's required to be in the insert for the drug package and distributing this kind of information all over the country. There is a physician's desk reference book, a private publication, that gives all this. Another example was the bill's requirement for a list of particularly dangerous drugs. They didn't pay much attention to our advice. I think it was Dr. Blair.

Now, the licensing of prescription drug manufacturers--that was their idea. At first blush, I thought that was a good idea, subject to one problem. That is to say, the new-drug provisions, in effect, were already requirements

for product licenses. They weren't called that--but you couldn't put such a drug on the market without HEW approval or clearance, so long as it was a "new drug." So it seemed to me that it was not sound to have these parallel provisions, license supervision for prescription drugs and then a new-drug section for all new drugs, including over-the-counter drugs. There'd be a great overlap. Apart from that difficulty, Billy Goodrich, who was Assistant General Counsel for Food and Drugs, opposed licensing on the ground that the sanction for violation--the suspension or revocation of the license--would be too drastic a power to use. He remembered that when he was still in the Department of Agriculture before this program came over to us (I think he was working on animal biologicals at that time--it was part of the Food and Drug service, I think) they discovered that a manufacturer had falsified, or had failed to report, that in its research on a biological, two hogs that they used had died in the process. There was fraud in other words. He says, 'Well, we had licensing, but we couldn't just put them out of business for that. That's too drastic!' (M: Too drastic.) So, our report did not oppose licensing in principle but pointed out that the same objective could be achieved by amending the new drug provisions of the act to remove the newness requirement and otherwise strengthening those provisions, expanding the factory inspection provisions and enacting a good manufacturing practice requirement. I still feel that the distinction between new drugs and non-new drugs is unsound. A so-called new drug after a while can become something other than a new drug, but at what point? There's no objective lines as to when that happens. It seems to me now that there ought to be straight Federal licensing of all drug manufacturers, that is, both establishment and product licensing for all drugs, instead of merely "new drug" clearance, and that it should cover both prescription and over-the-counter drugs. But I noticed in the newspaper the other day that the AMA wants to repeal even the existing

efficacy requirement for new drugs.

M: So you now feel--?

E: I now feel--I think we--we should have acceded to it if we could avoid the overlap with the new drug provisions, although it probably would not have gone through anyway. But Billy Goodrich felt the way I have stated, and I think he probably persuaded the Food and Drug Administration to that effect, and we all deferred to their views on this, although, as I have pointed out, our report did not object to licensing in principle. And so that idea, at least that provision, came from Kefauver. We were not proposing this. As a matter of fact we were, in effect, very gently opposing it as a practical matter.

M: I--I have the feeling that the substitute amendment to the licensing requiring registration...

E: If you are referring to the Committee substitute, to what became section 510 of the act, I think that was an industry proposal. FDA was cool toward it, though HEW may have supported it.

M: But I thought it was a good compromise.

E: That didn't stem from Kefauver or from us. (M: No.) In fact, that didn't get in until the committee acted on it. Am I correct about that?

M: I think you're right. He kept the licensing--

E: And incidentally, after he got all that opposition on licensing, what did he do? His subcommittee then came up with amendments to the full committee on it--with amendments to the bill which, first of all, changed the nomenclature. They called it "registration." This is different from the registration

provision that is now in the Act--section 510--and I'll come to that later. It had nothing to do with it. He called it "registration" but it was, in effect, licensing. But he provided for suspending or revoking that registration only through court action initiated by the Secretary. And to us that was just unthinkable! To have to go to court de novo to try to get a license revoked or suspended!

M: What does de novo mean?

E: It means that instead of a court merely reviewing our hearing record, and our decision based on that record, as to whether we had a substantial basis in the record for our action, the court--and maybe a jury--would hear all the evidence anew and then make a decision on the basis of that evidence.

M: Which would be terribly slow!

E: Not merely that. This is the kind of thing that is peculiarly dependent on expertise in the particular field, and decisions of that kind should be made by the expert regulatory agency, subject only to judicial review on the basis of the administrative hearing record under the substantial evidence standard.

M: And this is a sign of their lack of expertise? Kefauver's drafters' lack of it?

E: No. I think this was to be a compromise. They wanted to try to get it through with that compromise, but that would have been worse than nothing and would have been a bad precedent for regulatory law in other fields.

Break

M: We're now to the summer and winter of 1961 when the Department is working on drafting its own omnibus bill. I was wondering if you could talk about it

a little bit?

E: Well, that did include the size of generic name on the label, did it not? (M: Yes.) And the standardization of names? (M: It did.) Because I haven't seen that bill for years. As I say, I'm inclined to think that the basic idea came from Kefauver, you know. And I think we said the same size and prominence at least as the proprietary name, did we not?

M: It ended up at half the size.

E: It ended up in that but I think in our bill we had it at least as large, did we not?

M: I don't remember.

E: Well it would be the same as in H.R. 11581--as introduced--you know.

M: Right.

E: But I'm inclined to think, although I could trace it perhaps, that I got that idea--I think I suggested putting it in. Now, maybe somebody else suggested it but I--

M: No. I think the written records clearly demonstrate that you championed that.

E: I did. And I think I got the idea from Kefauver.

M: And I think Goodrich and maybe John Harvey weren't too excited about the idea.

E: I think not, although they, of course, did support it once it was put forward or endorsed by the Department. And I think that this is true of the standardization of names. They were very cool to that. Now I do think that

the way that was written in the original Kefauver bill was bad. The way it was written in the final bill was not as bad, perhaps because we had some influence on it. The way we had it in our bill, I think, was much better than any of those. It was simple. It was discretionary. And so forth. And I put in quite a bit of study into the background of it. Why we should have it, you know. As I mentioned to you, I looked into the expert testimony from Doctor Miller, Director of Revision of the U.S. Pharmacopeia, and others. I read an article on the subject of generic names, and so forth. And maybe I'm mistaken--maybe Food and Drug was enthusiastic about it--but certainly not the way they had prepared their original draft report.

M: No. I think you're right.

E: But the way the final report came out--and I wrote this--the objective is really endorsed. It is not equivocal on that at all. It doesn't say, 'If it's enacted, we'll do the best to administer it.' But it does suggest--and it gives the reasons why--that this power should be a residual power, although we shouldn't state that in the law. That we hoped that the voluntary system that was being improved at that time--under pressure, I believe, from those hearings--

M: There's no doubt that the AMA and the PMA were snapping to--trying to--

E: Ah--that it would be much preferable if that voluntary system could work without having us get into that to the extent that it wasn't necessary to do so in the public interest.

M: Right. I meant to ask this question earlier in regard to the report. Could you make some comments on the patent provision. I'm sure you spent much time in discussion as to what to do with these patent provisions.

E: Well, the patent provisions--let's see. Let me say first by way of background. You asked about (mild chuckle) my qualifications. I am not a patent lawyer. I did not have patent law in law school. And I don't consider myself at all an expert on patent law. However, when I had to address myself to this bill, I felt I owed something to the subject and I delved into the subject, giving it as much time as I could devote to it. And I discovered, to my regret I might say, that I thought that even apart from the duties that certain of these patent provisions would cast upon our department--it was defective and unsound in part in achieving what the Senator was after. I am referring to that part of the patent provisions that would bar the granting of a patent for a drug--I think it was limited to prescription drugs--if it was for a molecular or other modification of a drug or for a combination of drugs, unless the Secretary of HEW, after such tests as he might make or caused others to make, found that it had a significantly greater therapeutic value than the drug from which it was derived. And this is a very complicated matter. And so I felt it was necessary, in order not to encumber the Secretary's part of the report too much, I felt it was necessary to put much of the analysis of the defects I'd found into a staff memorandum, to be referred to in the Secretary's original report and enclosed with it. And because we were trying to be as sympathetic to the Senator as we could--the line was to be just as easy on him as we could, I think--I made that staff memorandum, which I wrote, just as gentle as I could, but I still felt duty-bound to point out what I had found. And I might say that the staff memorandum was sent by me to the Patent Office for clearance to determine whether it was sound. A bright career official in the Patent Office--I think his name was Federico--read it and cleared it. This may have been done by telephone.

REEL I, SIDE 2

M: It's been a while since I read your staff memo, but--so whatever you want to say about it--go ahead--

E: Well, about the staff memo--it speaks for itself. Incidentally, it was interesting--that staff memorandum is referred to in the Secretary's report as enclosed and attached to the report and is referred to as something that supplements it. After Secretary Ribicoff had testified before the--was it the sub-committee or the full committee?

M: The subcommittee.

E: The subcommittee--(ruffles through papers) I don't have his testimony but anyway, he reiterated a lot of what was in the main report--he got a letter from Kefauver--probably prepared by Blair, I don't know--being annoyed at the staff memorandum and asking whether really this was part of the report and saying that there is an indication in the staff memorandum that it really wasn't part of the report because there was a reference in the staff memorandum to "the Secretary's letter." Well, I think I had gone on vacation by the time the report was cleared and the Secretary went up to testify. I had really done all the work on it but Sid Saperstein--who was in the Division and later became my successor, incidentally, in the Deputy job, and ultimately as Assistant General Counsel, after I retired--he sort of followed through in my absence. And the Secretary's reply to Kefauver's letter about the staff memorandum was thus prepared while I was still on vacation. It says: 'You ask whether the Supplemental Staff Memorandum attached to this Department's report on S 1552, (1) is to be regarded as part of that report and (2) expresses my "views on the subject." This memorandum, which is referred to in the Department's report on the bill, was developed by our legislative staff solely in an effort to be helpful to

your Sub-committee in pointing up some ambiguities and uncertainties which they saw in some of the language of this part of the bill, and to suggest some improvements in the procedural provisions of this part of the bill.

It was not intended to be in any way inconsistent with my testimony or with the Department's report on the bill and we do not so interpret it.' (Heh!) It was a cleverly written letter.

M: He made that--made that clear.

E: Yeah. They later had testimony from the Commissioner of Patents which pointed out some of the difficulties in part, although not as pointedly. The way I did it in the staff memorandum was partly through a Socratic questioning. But it didn't help. Instead of being grateful for assistance of this kind, they just stuck by what they had. They changed other parts of it--they changed the procedural aspects, y'know. Well, they lost everything. But, they wouldn't have gotten it anyway.

M: Yes. Apart from the political--

E: Apart from the--yes. But it's unfortunate because I thought that that part about therapeutic efficacy--?

M: Value--?

E: Value was basically unsound because you don't get a basic patent for a drug as such. You get a patent for a chemical compound, or for a process in making it. If it's for the product itself, it's for a chemical compound or, in the words of the statute, a "composition of matter." This is what the "claim" for the patent would cover, regardless of what the "specifications" would show as to the usefulness of the compound. Yes, I suppose that if the specifications showed usefulness of the product as a drug, you could argue,

'Well, that's a patent for the drug,' within the intent of S. 1552. But in the light of this proposed kind of law, patent lawyers would strive to avoid using this kind of specification if they could avoid it--find some other utility. So basically, the problem should have been tackled, in my opinion, quite another way to achieve his purpose.

M: Were you sympathetic with his purpose?

E: Uh--well--

M: The purpose being to eliminate "me-too" drugs?

E: Well, if the "me-too" drugs were nothing but the same thing, but with some sufficient change to get a patent on it, so that the "me-tooer" could get a 17-year monopoly on it. But I don't know whether you'd call this a "me-too" drug because it would, I think, usually be the same manufacturer who would do this--so he'd extend his monopoly (M: right). Well, if that really could be cured in that kind of way--yes, I'd be sympathetic to it. (By the way, in recent Supreme Court decisions, Justice Douglas used the term "me too" to refer to pre-1962 drugs that manufacturers had, without applying for FDA clearance, marketed in reliance on similar or identical cleared drugs made by them or other manufacturers, on the assumption that the "me toos" were not new drugs when they were marketed.) But, in the first place, Kefauver didn't just bar molecular changes. You see, he said molecular or other modifications--although he didn't follow through on it in his procedural part. And he added any combination, meaning a mixture, of drugs. A molecular modification or other modification of another drug, or a combination of drugs, can result in some of the greatest improvements. And also, you couldn't get any patent on it unless it really rose to the level of invention. Something that was obvious to one skilled in the art.

M: Obviously the Kefauver people felt that that was not the case. What you're saying is that their device for trying to regulate this problem was just fraught with so many problems.

E: But anyway, if they wanted to do what they did, I think it might be done in a different way. Let's see! For instance, the law might be amended to say that a patent on a composition of matter would not confer patent protection with respect to the manufacture, sale, or use of the substance as a drug, if that substance was merely a modification of another substance that was already being marketed or used, or capable of use, as a drug, unless the Secretary had found that the modification had significantly greater usefulness as a drug than the unmodified substance or had, as a drug, usefulness of a kind, or for certain patients, not possessed by the unmodified substance. I would not strictly limit it to a therapeutic usefulness (in the narrow sense), for reasons stated in the staff memo. Something along that line. So you wouldn't bar the patent but you would bar its exploitation for drug purposes unless there was a real advance in the art.

M: I see.

E: I don't know. This would seem to me to be an obvious way to get around my difficulty. But maybe there's a flaw in it, because I never tried to tell him how to write his bill on that matter. I just pointed out what I thought was wrong.

M: I have the same problem that you do--even more so--that I am even more removed from being a patent expert so--(E; chuckle). Maybe we'd better go on. What, what about his primary patent provision? What was the thinking on this?

E: You mean, the other two provisions on patents? You--I think you asked for my attitude--was it?

M: Well, I just wonder what--uh--not only your (E: what I thought about em?) attitude, but what other people were thinking about them--(E: yes--well, now, first of all--). Especially compulsory licensing.

E: Yes. First--let me brush aside the one on the amendment to the Sherman Act. And incidentally, that one on the Sherman Act was the only provision in the bill that was the basis for getting the bill to his subcommittee.

M: That's right. That's right. And it came first. (chuckle)

E: It came first. (M: For that reason.) On that one, we, of course, acknowledged that we had no special expertise in the field and that the provision was still under study, primarily by the agencies charged with enforcement of antitrust laws. Suggestions were made by the Justice Department--through its Antitrust Division--that this could be handled in a different way. They were opposed to special treatment, under the antitrust laws, for particular products. But, at any rate, they proposed handling this in a different way. And I think Kefauver modified the Sherman Act provisions later or tried to. Now turning to compulsory patent licensing--the provision, as you will recall, was to limit the duration of the patent monopoly to three years after the filing of the application or, in the case of a "new drug," to three years after the clearance of the new drug for the market; and for the remaining life of the patent, to make it subject to compulsory licensing--at an 8% royalty--at the request of any so-called qualified applicant. And a qualified applicant was anyone who was a Federally licensed drug manufacturer under another provision of the bill. This compulsory patent license proposal was one of the provisions of

the bill--I would say the provision of the bill--that I had the greatest difficulty with from the standpoint of policy. Naturally, the objective of trying to get more competition everyone would agree with. At the same time, on the part of the industry and many other people there was a fear--and I was afraid and others were afraid--that this might have a very serious adverse effect on the incentives to research. In other words, the incentive was that if the manufacturer did achieve a patentable discovery, after spending perhaps millions in research on a particular thing, he would have a monopoly for the 17-year life of the patent. Under the Kefauver bill, he would get an unrestricted monopoly for three years at most. Incidentally, as I have said, the three years would date back to the date of the patent application or, in the case of a "new drug," to the date the new-drug application was approved under the Food and Drug Act. Yet a patent might not actually be issued until more than three years after the patent was applied for, and yet, under the Kefauver bill, the period of pendency of the patent application would be charged against the effective period of the patent, unless the drug were a "new drug." This provision of the bill was limited to prescription drugs, but a "new drug" might or might not be a prescription drug. There was great uncertainty about all this, in my mind certainly, and I felt that really our Department didn't know anything about that subject. I might say in passing, incidentally, that the draft report that I got from Food & Drug originally before I wrote a version for the Department pointed out our lack of expertise in this field. And, essentially I wanted to say this on our behalf--and I had written about a page or a paragraph on it saying--expressing sympathy with the objectives of the proposal but saying that this was a matter on which we had no special competence and that we deferred to others that were more qualified to pass on it. On the other hand, Dean Coston, particularly--who was one of the deputies or a Special Assistant to Wilbur

Cohen who was then Assistant Secretary for Legislation--felt, I think, inclined the other way. He felt inclined to say, in effect, 'Yes, it is a good idea.' Well, the Budget Bureau meantime consulted the Commerce Department and the Patent Office, of course, which is in that department, found flaws technically. And the Budget Bureau also consulted the Council of Economic Advisers. The response of the Council of Economic Advisers, of which the Bureau sent us a copy, was quite sympathetic. I have quoted it rather at length in a briefing memorandum. (M: I remember.) They suggested a possible alternative approach toward the same objective. And, uh, I remember calling the person in the Council of Economic Advisers who was responsible for having written this and saying, 'May we quote you on that?' Because I felt it would be nice if we could. I would have liked to put that in the Department's report, saying, 'We don't have any special competence on this matter, but here's what the Council of Economic Advisers has said.'

M: As I remember, the Council of Economic Advisers, on the whole, were favorable.

E: Yes.

M: To Kefauver.

E: Yes. I said, 'May we quote you on that?' And he said, 'I'm sorry, but we've just said this for the information of the Budget Bureau and you people, but our policy is that this cannot be made public.'

M: Do you have any idea why? Do you think that--

E: Well. I can see why--I can see that an adviser frequently feels much freer to give advice when he knows that what he advises will be kept confidential.

And I might say this is part of the reason that President Nixon gave for refusing to divulge advice given to him in confidence, although he has not been consistent about this.

M: I think that this is a very real--

E: This is a very real consideration. On the other hand, I said, 'This is a Hell of a note!' (M: chuckle) I said, 'Why you know this is not the kind of thing that you should be afraid of having published. You ought to be able to stand behind it.' 'No, we can't do it.' I said, 'All right.' It seemed to me that, under those circumstances, all we could say was--what I had said in the draft, you know, that is 'We have no special competence; we have to defer to others!' (M: heh-heh-heh-heh)

M: You like it but won't support it.

E: Now this is the one thing in my draft of our report--aside from some minor things--that was changed. Dean Coston rewrote this. And rewrote it in a very clever way. After stating that the bill's provisions to improve the Food and Drug Act would be 'conducive to more active and effective competition in the sale of drugs, with consequent benefit to the consumer,' he said: 'The antitrust and patent law provisions of the bill are obviously designed with the same end in view. They--the antitrust and patent law provisions--are, at this writing, still under intensive study not only by this Department, but more especially by those agencies that are primarily conversant with problems of price competition because they are charged with enforcement of our laws against monopolistic practices and combinations in restraint of trade. While we do not feel equipped at this time to appraise their probably effects in terms of their economic objective or, on the other hand, in terms of preserving desirable incentives to research.' Now mind you,

we said we're not competent even to appraise their effect on preserving desirable incentives to research. We should make clear that omission of detailed discussion of these aspects of those provisions from this report does not betoken lack of concern for the objective to which they are addressed. We recognize that this bill would profoundly affect current marketing, promotion, and research in the drug industry. We are, however, confident that the demand for medical service and drugs will expand greatly in the years to come. This demand, coupled with an outpouring of the results of medical research into the prevention and cure of disease, will undoubtedly sustain a healthy expanding, and prosperous drug industry. It is of the first importance that all reasonable steps be taken to prevent exploitation of the public in the sale of what often is literally a "necessity of life." Now this is extremely clever--beautifully written--but internally contradictory.

M: Yes. (chuckle)

E: Actually, in saying that we're confident that the demand for medical services and drugs will expand greatly in years to come and that that demand, coupled with an outpouring of the results of medical research--and so forth--will undoubtedly sustain a healthy and expanding and prosperous drug industry, I think he meant to convey the implication, 'Well, even if your proposals in the patent and antitrust fields have an adverse effect on research, with all the other things, why, the industry will be all right.'

M: Yet, this is what's so maddening about this report. On almost every point, the Department agrees--Ribicoff agrees with what Kefauver is after, but right down the line he says, 'But we can't support anything in your bill.'

E: Well--it isn't anything. Several things--

M: Not any thing but--

E: We fully went on to support the bill to the extent that we could.

(M: Right.) But it's interesting. I think it's written in a tone which is not quarrelsome and very cooperative. But here's something--here's something--and I cannot remember whether I wrote this peroration or not but I think I was asked to. We could not end up with all these comments, to the extent they were adverse, and so we had to give it a more favorable tone at the end. So it says, 'This concludes our comment on the specific provisions of the bill of special concern to us. In summary, we strongly favor the objectives of the bill, and we urge favorable consideration of the amendment of the Federal Food, Drug and Cosmetic Act proposed by the bill, for the administration of which we would be responsible, subject to the modifications (M: laughs) suggested and comments contained in this report.' In other words, 'yes, but no!' (M: laughs--hard) But don't say 'No.' (M: ends laughter) And then, in parentheses, '(While the above comments on the bill include observations as to some deficiencies or problems of a technical nature in this bill, and our staff happened to note a few additional typographical and similar errors, the bill has not been reviewed by us with a view to perfecting it technically.' I didn't want to throw in a lot of drafting points showing how. 'If the substance of any provision, for the administration of which we would be responsible, is favorably considered by your Committee, we should appreciate an opportunity to review it further from the point of view of its technical adequacy and to make suggestions accordingly.)' I felt I had to put that in even though it is in parentheses because there were some pretty sad drafting points that should be taken up with the committee staff if the proposals of the bill were otherwise favorably considered. As for the rest, except as I have noted, I

wrote this report. I did utilize some points from the Food and Drug Administration's draft, such as some of the difficulties inherent in the patent provisions on therapeutic value, its arguments about why we didn't need to require all that information, etc. I used that though I wrote it somewhat differently maybe.

M: Do you have any further comments you'd like to make on the Department's omnibus bill?

E: Well, the decision to put it all in one bill was simply a policy--tactical, strategic, quasi-political--decision at the top level. Rather than have a drug bill--or drug and factory inspection also--and then to have a food bill and so forth--and also, the factory inspection proposal that we had wasn't limited to drugs; it cut across the board. So there was also the problem into which bill to stick it if we had more than one bill, or do we put it into every bill? What we did, though, when Kefauver effectively, through influence at the White House or whatever, prevented us finally from sending up an Administration bill or bills, was first of all to split our bill into--(riffing and looking through papers)

M: You split it into two (E: What?)--you split it into two sections, 11581 and 11582.

E: --into two bills, which eventually were introduced on the House side, and send those two bills only to the House side--

M: Right.

E: The bills were introduced by Chairman Harris as H.R. 11581 and H.R. 11582. And these bills were the same, when you put them together, as our omnibus bill, although, because they were split, I had to make some

drafting adjustments and made a few other improvements in the bills.

Secondly, on the Senate side it was decided to give Senator Hill just one bill--not to have any drug bill of our own at all. But just a food--um--let's see, that was called--

M: Food--

E: What?

M: Food and Cosmetics Bill--

E: (Riffles through papers--vigorously!) It was called the Cosmetics and Therapeutic Devices Amendments of 1962.

M: Now you gave this--just that part--to Lister Hill--

E: Just that bill to Senator Hill. It did not cover drugs. But it did have a factory inspection section in it with across-the-board coverage of all articles covered by the Food and Drug Act, including drugs. That provision was designed to improve what we could look at across-the-board in factory inspection--including consulting laboratories. And I think we put into that bill the provisions on biological drugs that we also had in our omnibus bill. Now, its very interesting that these three bills were not called Administration bills by us. Hill, incidentally, never introduced the bill we sent him.

According to an April 13, 1962 memo from Wilbur Cohen, at that time Assistant Secretary for Legislation, to Meyer Feldman who was then Deputy Special Counsel to the President, Senator Kefauver agreed to certain amendments proposed by the President, evidently those proposed in the President's first letter, dated April 10th, 1962.

M: Oh yes, yes.

E: 'Senator Kefauver's staff suggests that they be transmitted to Senator Eastland by Secretary Ribicoff urging their adoption.' And the memo goes on to say: 'With the adoption of the President's amendments by the full committee,' if they are adopted, 'S.1552 can be considered an adequate legislative vehicle carrying out the recommendations relating to drugs contained in the Consumer Message. To carry out the remainder of the President's program, we propose the following: (1) Submit to Senator Hill a bill providing--' And then on--you know-- (M: Um-huh.) --'(2) Submit to Chairman Harris of the House Committee on Interstate and Foreign Commerce two bills, one paralleling as closely as possible the Kefauver drug bill and the other comparable to the bill we propose to send to Senator Hill.' Now, in that he misspoke himself--or miswrote himself (M: chuckle). The one to Chairman Harris did not parallel as closely as possible the Kefauver bill, you know. (M: Right. Right.) It was really what was in our omnibus bill so far as drugs and factory inspection were concerned. It was better drafted, as to organization and, in large measure, as to its content and that is reflected in the final law.

M: Whose idea was this strategy?

E: Well. It was evidently cooked up at a level above mine. I was not privy to the conversations, but it must have been between Wilbur Cohen and Meyer Feldman and probably--possibly the President--I don't know.

M: Sonosky likes to claim that he--

E: And Sonosky was undoubtedly privy to it.

M: Um-huh.

E: Now where it--how far he was in with it--he was in with Feldman--
I don't know. He thinks he was responsible for that?

M: Well he thinks he's responsible for a--a--

E: For the strategy.

M: For quite a lot.

E: Well, I think he is--

M: (chuckle)

E: And he might well be the one that suggested this. And he drafted
this memo from Cohen to Meyer Feldman. I can see that from the file copy.
One went to me.

M: The fact that--yes, I'd like to see that. I don't think I've seen
that document.

M: Sonosky suggests that this was a highly unusual strategy. In other
words, to send part of a bill to the House and virtually use another bill
in the Senate.

E: Yes, what we had done there was unprecedented. Now, it was also
unusual to send--when we sent up a bill officially--a draft bill for the
Department--it would be most unusual to send it only to one house. We
would usually, normally, send it to the Speaker of the House--and to the
President of the Senate, who is the Vice-President.

M: Yes.

E: And it would be so addressed, and then would be referred to the

appropriate committee. One exception we have made is in the case of bills to amend the Social Security Act--we have generally sent those only to the House side at first--particularly if they amended the tax laws--but even otherwise. Under the Constitution, a bill to raise revenue has to originate in the House but, as I say, we have not limited this procedure to those Social Security bills that contained tax provisions. So that was an exception. However, in the instance we are speaking of, the transmittal letters were most unusual. In fact, unprecedented. The one to Chairman Harris said--and I think I have a copy here--(ruffles papers) that we are sending, 'in the form of two draft bills, the legislative language which' --and I am still quoting here--'which you requested to carry out various proposals recommended by the President in his recent special message on consumer protection.' (laughs) In other words, it doesn't say that these are Administration bills; it doesn't say that these are bills proposed by the Department; it gives the impression that these bills were really requested by Chairman Harris, so that the Chairman, who was Chairman of the Interstate and Foreign Commerce Committee of the House, could then proceed with his committee in his consideration of the President's Consumer Protection message.

M: In other words, Kefauver was causing enormous problems.

E: Yes. Absolutely. Now, the letter to Senator Hill, the Chairman of the Labor and Public Welfare Committee of the Senate, transmitted only a draft bill, the Cosmetics, Therapeutic devices, and Factory Inspection Amendments of 1962. I don't recall whether the letter explained the reason why we did not submit a drug bill to him. (Senator Kefauver claimed that he had cleared with Senator Hill the introduction of a drug bill designed to go to the Judiciary Committee.) And there was then a memorandum from my immediate

superior, who was then Assistant General Counsel and later became Deputy General Counsel.

M: Was this Willcox?

E: No. That's Reg Conley. Willcox was General Counsel.

M: Oh.

E: Conley is retired now, too, you know. A very wonderful man. They both are wonderful men. Mr. Willcox is also retired from the government service. Anyway, there was a memo--which I had drafted--from Conley to the Budget Bureau transmitting copies of the two letters sent to Harris and Hill. And the memo states that 'the transmittal of these draft bills, requested by the Chairman of these two committees, was discussed by Assistant Secretary Cohen with Mr. Feldman, Deputy Special Counsel to the President,' and that copies of the letters and bills had been furnished to Feldman. The letter adds, 'Senator Kefauver, the sponsor of S.1552 also has been apprised of the fact that the above-mentioned draft bill was going to Senator Hill.'

M: Was that true?

E: Oh, undoubtedly it was true.

M: That Kefauver was advised that--

E: Apprised.

M: Apprised.

E: Orally, if not in writing. I have a note about a somewhat later memo from Cohen to Feldman, dated April 20, 1962, which states that the action taken with regard to sending draft legislation to Senator Hill had been

cleared by telephone with Senator Kefauver.

M: Uh-huh.

E: But it doesn't say that Kefauver was apprised of the other two draft bills going to the House side.

M: Uh-huhh.

E: And whether he was or wasn't, I don't know. He later surely was. The memo from Reg Conley to the Budget Bureau--it was to Philip Sam Hughes, then Assistant Director for Legislative Reference who sometime after being promoted to Deputy Director retired and now is in charge of the GAO supervision of election irregularities. The memo points out that 'the two draft bills sent to Chairman Harris together embody the proposals contained in our draft "Food, Drug, and Cosmetic Amendments of 1962."' (The Budget Bureau evidently had that already.) 'Plus an amendment to the Federal Trade Commission Act embodying the provisions of the Dingell Bill (H.R. 6471) with the change (as to drug efficacy) recommended by the President in his consumer protection message and by the FTC.' I might add here that the memo states that several drafting changes had been made, in part as a result of the division of the omnibus bill into two bills and in part to effect certain drafting improvements. The memo also adds that a section modifying the grandfather clause of the Food Additives Amendment of 1958 in substantially the same form as one submitted to the House Committee in 1960, was added to the bill containing the feed additive amendment in order to complement that amendment--and it gives the reason for it. I might say that that was not in the drug bill but that was done in the other bill. Yet, the Committee then put that particular feed additive amendment into the drug bill. And it became part of the final law.

M: Was that the DES provision?

E: Yes, but that is not limited to DES.

M: Uh-huh. May I ask you what you're reading from?

E: I'm reading from notes that I made a few days ago to refresh my recollection, but I think I have that memo here (ruffles through papers). Now. Yes. I have it right here. The memo adds this paragraph: 'The draft legislation sent to Chairman Hill is limited to a single measure because of the special situation created on the Senate side by the pendency of the Kefauver bill (S.1552). Accordingly, the draft bill furnished to Senator Hill does not cover drugs except for the section on biological drugs (section 404) and except for the inclusion of Title III to clarify and strengthen the factory inspection section of the Federal Food, Drug, and Cosmetic Act, which cuts across the board. (This bill, since it includes the feed additive amendment, also includes the modification of the grandfather clause of the Food Additives Amendment of 1958.)' This is a related matter.

M: It's very clear that Kennedy's letter dated April 10 urging that the bill be passed came conveniently just after the subcommittee had lopped off the patent provisions.

E: But not all of them. The McClellan Committee didn't recommend against all, I think.

M: No--not all of them. That's true.

E: On the therapeutic value it didn't completely (M: That's true.)--try to strike it down. The committee--the full committee did.

M: But the point I'm getting to is the strategy was 'We're going to use

S.1552 as the vehicle in the Senate, but first we've got to get this patent business out of there.'

E: Well, now, I don't think we actually opposed the patent amendments, although the Secretary's report on the bill, and our enclosed staff memo, pointed out bugs in the provision on therapeutic value. You know what I mean? We just said we couldn't take a position on them. Now it may be that President Kennedy wanted them out, although his letter of April 10 actually suggested amendments to the provisions on therapeutic value.

M: Okay. But you don't have any personal knowledge of that?

E: No, I do not, not about that alleged strategy.

M: Okay.

E: But--nothing--it was nothing that we said or anyone in the Administration said except maybe for the Commissioner of Patents who pointed out defects. In nothing did we say we were opposed.

M: Right. But the point is that the McClellan Committee lopped off these two patent amendments and then as soon as that's done, the letter arrives and the letter says something to the effect, 'We see that the patent amendments have been removed, but let's move on with the other provisions.' But as far as you know, you don't really know what the Kennedy Administration's attitude was towards the compulsory licensing--in other words, what their thinking was on this?

E: I don't know what the President's attitude was. Or the White House attitude, if you want to call it that. I think that no one could tell what consequences might ensue from such a provision. I do know, though, that, as I have pointed out to you, we went rather far in that substitute paragraph

of our report that Dean Coston had written on the patents--went rather far in being as sympathetic as we could be without really affirmatively endorsing it.

M: Right. You certainly left the door open.

E: Very far.

M: Right.

E: Yes. (M: Right.) Now this was not my doing. I would have left the door open all right in what I had written. What I would have said is, 'We're just not competent to decide the effects, good or bad, on research.' I said "good or bad" and I think that's still in the Secretary's report, that phrase "good or bad."

M: Right. Well, I now remember that Wilbur Cohen made the point when I interviewed him that he felt that Kefauver just did not have the political votes to carry this controversial point and so for this reason, they didn't pursue it.

E: Oh, didn't pursue it--

M: Didn't pursue it.

E: Was he indicating, whether he favored it in principle or not?

M: Well, I think he said he felt he favored it in principle. He was sympathetic to it but he just didn't think the votes were there.

E: Yes. Well, I personally couldn't tell whether it was a good thing or not. Because I just didn't know what it--it might have terrible consequences for research--it might not. You know. I just didn't know.

M: Yes, yes.

E: And it would be taking a hell of a chance, a big chance, if that became law without one having a better idea of the consequences. Now there were examples given from other countries as to what kinds of legislation they had.

M: Right. Right.

E: You know all about that.

M: Well. Could we move on to the famous "secret" meeting, and--

E: You say 'meeting' in the singular. Right?

M: Well.

E: Now which meeting are you referring to--which phase?

M: A very good point.

E: Are you referring to the phase preceding the report--the first report of the committee to the Senate--you know, the first version of the bill?

M: Well, first I'd like for you to talk about the events leading up to the "secret" meeting which took place in June of 1962.

E: Well, of course, you had had the President's letter to Eastland.

M: Right.

E: Right.

M: In April.

E: Yes. I don't--I--Eastland was approached, I suspect at least by Wilbur

Cohen--but--I suspect even by the White House. You know. We--we wanted legislation. We wanted to--there was an impasse, I think. Now, I might say that the drug industry itself--the so-called ethical or prescription drug industry--wanted legislation--as I understood--not necessarily because in principle they favored having tighter controls, but because all of the adverse publicity they had received during those extensive hearings on the pricing practices--administered prices in their industry--had given them a black eye. They wanted to get the damn thing--they wanted to get it out of the way, they were willing to have legislation and support it--within limits. (M: Right.) They were willing to go fairly far from their standpoint but not beyond certain limits, and they were going to try to contain it as much as possible. Now, the Administration, of course, we, as a department, in the public interest, and the President--we wanted legislation. Even though, as it turned out, it was not started formally as an Administration bill. We wanted legislation to accomplish the things that had been in the Consumer Protection Message and that were in the bills that we had drafted, and important parts of which were reflected in the Kefauver bill--plus certain additional ones that we wanted to see in there. Certain things in the Kefauver bill we didn't want--didn't want to have there. Now, someone at a high level got in touch with Senator Eastland, the Chairman of the Judiciary Committee. That's sure. Now, whether it was Wilbur Cohen or the White House or both, I don't know. And Senator Eastland, I think also favored legislation, as did Senators Hruska and Dirksen. They were all minded to get out a bill. And I think that Jerry Sonosky probably already had been up there personally talking with these men. Maybe Wilbur Cohen too. But I was not privy to those preliminary contacts if there had been such. But anyway, Eastland arranged to have a meeting, or meetings, I do not remember at this late date whether there were more than one. I think there were more. But let me tell you that I do not

think there were secret meetings that I attended. Jerry took me along when we came actually to addressing ourselves to what--to bargaining and negotiating about what was to be in the bill--not about patents, we didn't get into that in those meetings. As for their being secret, I don't know what is meant by that. Your meeting with me now is secret in the sense that it's a private meeting and we don't have it public.

M: Wilbur Cohen made exactly the same point.

E: Who?

M: Mr. Cohen made exactly the same point. He said, 'We haven't invited John Blair to come to the meeting.'

E: Now we could not--it was not our meeting. It was called or directed by Eastland, though I think Eastland was not present. (M: He wasn't.)--Pardon?

M: As I understand it, he wasn't.

E: Was not. It was arranged by him in his capacity as Chairman of the Committee in order to try to get the interested parties together as much as possible. And that meant our Department on behalf of the Administration; it meant the spokesmen for the Pharmaceutical Manufacturers Association on behalf of the ethical drug industry. Majority and minority staff members were also present. And I think we suggested--and I know I personally suggested to Tom Collins, who was Eastland's man--that they have Kefauver represented--I thought it would be a good thing. But no--no--Senator Eastland didn't think that--he thought that was not desirable, and I think it turned out later that, as I see it, that was a mistake.

M: Did he say why it was desirable not to have Kefauver there?

E: I think when Kefauver attacked them on the floor, Senator Eastland took responsibility for it.

M: Eastland--Eastland took responsibility for it.

E: Yes. It must be in the Congressional Record for that day.

M: Yes.

E: I cannot remember whether Senator Eastland explained his reasons.

M: Yes. I think I can understand what the reason was.

E: Well he--

M: --Felt that Kefauver just would not compromise.

E: Would not--wouldn't compromise and he would just obstruct things--they wouldn't get anywhere. (M: Yes.) I'm just guessing. But I think that was probably what he sincerely thought. Now I think it was a mistake in tactics. But anyway, we met across the table--and I think the original meeting was in the room off the Committee's hearing room, where they hold their executive sessions. I could be mistaken in my recollection, but I think so. Now there were present Jerry Sonosky and I from our Department. Present from the staff side, I think, were probably, I say "probably," because I'm not entirely certain anymore--I didn't make notes--Tom Collins who was Eastland's staff man on the Committee; I think Mr. Chumbris who was Mr. Dirksen's staff man or counsel; and I think Ronald Raitt who was Senator Hruska's assistant--I forget whether he was on the Committee staff, but he was an assistant to him. And for the Pharmaceutical Manufacturers Association, there was Lloyd Cutler, a very able lawyer, and I think Marshall Hornblower was with him already at that time--he was at later meetings, I know. And I

might say (chuckle) he has a nickname--'Whistle'--just call him 'Whistle.'
The name's Hornblower. (laughs)

M: And they call him 'Whistle.' Heh-heh.

E: 'Whistle'--also a very able and bright lawyer. And the only thing that I remember of that meeting or those meetings--at one point, I think, I was negotiating, with Lloyd Cutler while Jerry was pursuing a point with somebody else across the table. One big issue that I know I argued on with Lloyd was on good manufacturing practice. Another, I believe, was on their proposal to require only substantial evidence of new-drug efficacy. Incidentally, all or virtually all, the discussion, as I recall--best recall--I may be mistaken--all the real discussion was between Jerry and me on the one hand and--at least as far as I was concerned--those lawyers--or that lawyer--from the industry on the other hand--and not with Senate staff. I got the impression, both then and at later meetings, at this first phase and the second phase, that if the industry lawyers and we could agree on something or compromise on something, that would be carried back by staff to their principals but the staff just assumed that that would be all right and acceptable to the Committee--to the majority at least. I mean the actual majority, not necessarily the majority party on the Committee.

M: In other words, it was pretty much left to you and Sonosky.

E: Yes, except that I would not finally agree to anything without clearing with Sonosky, an Assistant to Wilbur Cohen. Jerry and I worked closely together, and as between him and me he was the policy man. Now, what I said about Committee staff is not any reflection on them at all. Because I think it could be assumed that whatever the Department and the Administration felt was sufficient protection for the consumer, if it was also acceptable to the

regulated industry, their principals would go along with. It isn't so unusual for a committee or committee staff, to try to have the interested parties come to a resolution of their differences, subject to the review of the Committee. So that is no reflection on them. But I think that was pretty much the fact. I'll come to the later meeting later. One issue was on the question of the requirement of good manufacturing practice--how that should read. You see, they, the industry people, agreed that there should be some provision on that in the bill. And we wanted it in there, in a satisfactory version. Was that in the President's letter of April 10?

M: I can't recall.

E: I think that by then we had furnished language to the staff--you know, to Senator Eastland--to carry out the--. The President says, I think, in his letter, does he not, that the Department will furnish language to carry out his suggestions? Or am I thinking of his later letter?

M: I'm not sure. He says at the bottom, 'I have asked the Department of HEW (E: yes) to transmit to you promptly any additional recommendations to strengthen, clarify or improve the bill.'

E: Well.

M: What--was the purpose of the President's letter, to bring S.1552 more into line with the Harris bill?

E: Yes. Into line with what we wanted. (M: Yes.) And what he had recommended in his Consumer Message, too. And--this--I don't know that I ever saw that April 10th letter before it was sent. This is not true of the later letter. The later letter, dated August 3, 1962, particularly all the enclosures of legislative language, I drafted, except for one piece that

I'll mention. So anyway, we argued with the industry lawyers back and forth over the good manufacturing practice proposal. We wanted it the way we had drafted it for the Harris bill--although the Harris bill hadn't been introduced yet--or was it then? Well, wait a minute (M: yes, it had been--). Yes, it had been. Oh. All right. And we wanted the authority to issue binding regulations as to what was good manufacturing practice. And that was in our version. This was a very important point. And to that they were strongly opposed--the industry was strongly opposed. So what they, then, came up with was a suggested compromise--was to say, among other things, that we would have authority to issue interpretative regulations which were to constitute merely prima facie evidence of what constituted current good manufacturing practice. Well, I didn't feel authorized to agree to that, but this was where we left it--we could get no further concession--and I felt it was better than nothing--better than no express authority for regulation at all. It was a little stronger, I felt, than just to leave it without any reference to regulations. Mr. Goodrich, it turned out, thought it would be preferable to have no reference to regulations, relying instead on our existing authority to issue regulations 'for the efficient enforcement' of the Act. In retrospect, I think he was right. But anyway, that--that's as far as we came in the direction of an agreement. We didn't really reach an agreement. The other part of that paragraph that was in issue--really in issue--was whether, as we proposed, we should be able to look at personnel of the manufacturer in determining whether there was good manufacturing practice.

M: Yes. The qualifications of the personnel.

E: They, the industry people, were strongly opposed to that and prevailed with the Committee at that stage, although in the second phase a compromise on that was worked out which we eventually accepted together with a change

in the inspection provision to cover qualifications of technical and professional personnel. The other thing that I argued with him strongly was on new-drug efficacy. They were willing to put in the element of efficacy, but providing that all that should be required was "substantial evidence" of efficacy, including substantial clinical evidence. And at that point--I don't think that there was any definition of substantial evidence suggested. If it was, I don't remember it. It might have been. But I couldn't accept that, although I felt it was better than nothing. On the other hand, I might quite candidly say, although I did not tell them that, I had some reservations about our own position that if you had conflicting expert views and evidence on this--conflicting evidence--that it couldn't go on the market--it couldn't go to doctors even after adequate investigation, you know, after trial. I also was thinking somewhat uneasily about the Pasteur episode in history, you know, when doctors laughed at him. And to make this an absolute requirement, in that strong fashion, bothered me and bothered Mr. Willcox, too, I think. So I didn't feel entirely unhappy about the idea of some limitation on the efficacy requirement. On the other hand, a requirement of substantial evidence, just by itself, seemed a bit weak. And--uh--what are you looking up?

M: I thought I was--would look up--uh--my comments on the "secret" meeting.

E: Oh.

M: Uh--but go ahead.

E: I'd like to show you--well, shall we go ahead or shall I--?

M: Go ahead. Go ahead. I'm anticipating a question--

E: Yeh. So--we didn't really come to an agreement, but we left it there--

I've forgotten whether those were the two most important things. I think that we discussed inspection, too, at that stage, but it's just not very clear to me at this point. We reported back to the Department, I think, as to what was going to happen because we assumed that this was what the Committee probably would come up with and also that was probably the best that we could get from the Committee.

M: Were you generally pleased with--with the results?

E: Not--no. But--on--on the other hand, uh, I will not--when you say 'you', do you mean me, personally? I felt--uh--that it was better than nothing--better than--uh--what we had--uh--well! (small chuckle) Anyway, better than nothing. However--and I don't remember clearly just how soon--first of all, on the provision in the good manufacturing practice paragraph saying that we could issue interpretative regulations, Mr. Goodrich felt strongly that we would be better off if the bill were completely silent--if the amendment were completely silent on regulations so that we would simply rely on our general authority to issue regulations. We would, he thought, be better off that way than having a provision which limited us specifically to interpretative regulations with only prima facie effect, since a court might or might not agree with our interpretation and give the regulation less weight than it otherwise would. And he felt strongly about that, and I think he carried the day on that--uh--I didn't particularly argue it one way or another. I didn't care; it did seem to me better than nothing, but he felt otherwise and I now think he was right on that.

M: When did he--uh--voice his opinions?

E: Well it was--oh, he was present at the meeting with--

END OF REEL I, SIDE 2

START - REEL II, SIDE 1

M: All right, go ahead.

E: Well, before going into the matter of reporting to the Department, I notice in--in the--this in your doctoral thesis on "Estes Kefauver and the Drug Industry" (M: right, right) which you have just shown me. On page 306, this is apparently based on Harris's book, which I haven't read, though I have read his "New Yorker" articles--you say that we had been able to replace Kefauver's stringent licensing provisions with a combination registration and increased inspection program which would have accomplished the same goal--that of assuring the doctor that all drug manufacturers were competent. The change, it says here, 'included (1) a provision which required all drug manufacturers to register with the FDA and every registered establishment to be inspected every two years; (2) the inspection authority of the FDA would be increased but would not include financial, sales, pricing, or personnel data; (3) the FDA could deem adulterated any drug which was made or stored under conditions that did not conform to good manufacturing practice. HEW would have the power to define through regulations what those practices were.' Well, we took the position that the objective of the Kefauver provision on licensing--which, incidentally, was limited to prescription drugs--could be accomplished better, in the first place, through good manufacturing practice requirements whereby a drug that did not comply with those requirements would be deemed adulterated--and we would not limit that to prescription drugs--and secondly, through broadly widened inspection authority. And that is all. We never proposed a provision which required all drug manufacturers to register with the FDA. That was an industry proposal to which the Food and Drug Administration was somewhat cold. We did not object to it, but we did not come forward with recommending it. It did not originate with us and we did not affirmatively recommend it. And what is

more--

M: Nonetheless, that is what--

E: It was an industry--. What?

M: But nonetheless, that is what came out of the "secret" meeting.

E: It did not come out of the "secret" meeting. I think that that was proposed by industry--why should it come out of a secret meeting?

M: Well--I mean--it came out of this meeting. It--it was agreed that that would be acceptable to both sides.

E: Well, I don't remember whether it was--it certainly was not unacceptable to us, but it would not, in our minds, in any way have constituted any substitute for a licensing provision. We already had basic inspection authority and merely wanted it broadened as to subject-matter. The only thing that the registration provision did was to require every little bathtub manufacturer, as it were, the drug manufacturer out of a bathtub, to register and to be inspected every two years. The Food and Drug Administration, I think, felt they already knew who was making drugs. The provision didn't require registration of which drugs they were making at that time. There has been a more recent amendment about listing drugs--last year--which does that. But that's a different matter. And--uh--it was not part of a compromise about abandoning licensing provisions. We would never-- (M: But wasn't--but it--) our people--Mr. Goodrich, particularly, felt strongly that licensing was a bad idea because it was too--it called for a sanction that was so drastic it would never be employed. And our people felt that a really effective provision would consist of two things--a good manufacturing practice requirement, buttressed by authority to prescribe by regulation what's meant

by good manufacturing practice, and broad inspection authority. Now, about the exceptions to inspection--about financial data, yes, we agreed to that. We were not concerned with cost data and so forth--um--from our standpoint.

M: That's a perfectly understandable exception.

E: Sales data we did not--uh--object to--except that I had suggested--and at the later phase it was put in--a clarification that would authorize inspection of shipment data, which would really tell us something. As for pricing data--again, we were not concerned in our department at that time with that. Now as for personnel data--to except that from inspection authority. I don't think we ever agreed to that. And finally, in the second phase we managed to get it back in.

M: Right.

E: It was certain key personnel--the technical and professional personnel.

M: Well this brings up the whole problem of my trying to evaluate the amendments that came out of this meeting. On the one hand it seems to me that HEW--the Department--the Kennedy Administration--whatever--accepted these amendments and that these amendments are--as Sonosky said--'Amendments that we can live with.'

E: Well, we certainly could live with the registration provision, but it did not give us anything that we felt at that time we needed.

M: That you needed--

E: So--surely it was acceptable. We ought to inspect everybody--at least every two years. Actually, we haven't been doing it--maybe now we do--I don't--I don't mean "we"--I'm no longer with the Department--(M: Yeh. Yeh. I know

what you mean.) It's a question of manpower. (M: Right.) The industry wanted it because the manufacturers whom the Pharmaceutical Manufacturers Association represented, by and large, the large manufacturers, they said, 'Well, we are being inspected all the time! Let's make (slaps paper) those small ones be inspected too--those bathtub manufacturers!' (M: Right.) And they, the PMA, were the ones to come forward with it. And so, I don't know whose idea this was--who sold this to Mr. Harris for his book--maybe Dr. Blair had that idea. He may have gotten it from the first committee report of the Senate Judiciary Committee on the bill, which states: 'In lieu of the proposed licensing system, the committee substituted a new registration provision, strengthened factory inspection authority and quality manufacturing controls.' That's on page 12.

Now about the time provisions for clearing a new drug. I don't remember whether that was part of the discussion or not, but I think we were prepared to compromise on it so long as two things were assured, namely that a new drug application would not ever be automatically approved, no matter what time had passed, and secondly, that time directives would be imposed on us, if at all, only for the period before the hearing and not at the hearing stage. This, essentially, is how it read in the original version of HR 11581. And you will notice that the final law doesn't provide for automatic approval of an NDA and while it limits the time within which we must go to hearing if one is requested, it does not have a time limit as to the length of the hearings.

M: Yes. I think there is a very complicated clause--there's a time limit--

E: Well, it has a time limit as to how soon after conclusion of the hearing the Secretary must make a decision, but that is within his control because it runs from the date fixed by him for filing final briefs.

M: Right.

E: We'll come to that later--

M: 120 days--is in this omnibus--

E: We'll come to that later. But not as to how long it takes to have the hearing.

M: But is it not true that after this meeting that there was not provision for this?

E: For what?

M: For preventing automatic acceptance of a new drug?

E: Well we didn't agree to that.

M: Well, the point is that (sigh) that Kefauver was certainly given that impression.

E: Well, I don't care what impression he was given. I can tell you (small laugh) that we didn't agree to that!

M: Well, then, why--

E: Did Sonosky tell you that we agreed to that?

M: He said that it was--he said it 'was something we could live with.' This is the part I don't understand. Why even go into this meeting.

E: I suppose we can live with almost anything. We lived with the preceding law. Moreover, the first Committee version of the new drug clearance procedure would itself have been a vast improvement over existing law. It would have excluded the hearing time from the time limit, though it set a time for commencing a hearing after notice. The FDA would have had to be

negligent in letting an NDA become 'effective' by default by mere expiration of time. In fact, even under the old law, an alert FDA would not have done so.

M: So then you're saying that HEW did not support what you and Sonosky worked out.

E: We didn't work out what you're saying. (turns papers) I mean, at least I don't have any such recollection. It's unfortunate that I didn't keep a diary, you know! But let me, are you saying, where is it? (ruffles through papers) The bill, as you thought, would have what, now?

M: Okay. What I'm referring to is that evidently this meeting--the so-called "secret" meeting took place on a Friday.

E: Well, I thought there was more than one meeting, but I could be mistaken. Maybe there was--

M: Well there were meetings leading up to it.

E: Mm-mm--

M: As I understand.

E: Well, I don't remember--

M: Evidently on the following Monday, when the full Judiciary Committee meets, and I understand that you were there and Sonosky (E: yes) was there-- the drug company representatives--I guess Dirksen actually presented these twelve amendments--

E: I don't remember who presented them. Incidentally, industry representatives were not present. This was an executive session of the Committee.

M: I believe it was Dirksen who presented the amendments. And that these,

evidently, were the agreements that had been worked out in the preceding Friday (E: well, maybe this is--). This, of course, is when Kefauver blows up and he says--and he turns to Sonosky and he says, 'What's the position! What's HEW's position on this?' And Sonosky says, 'I'm just here as a technician.' And so that's when Kefauver runs out and calls Cohen and Cohen says,--uh--well, before that Kefauver had asked Sonosky, 'Has Cohen seen these?' and he says, 'Yes.' Then Kefauver runs out and calls Cohen and says, 'Do you support these? Have you seen these?' And Cohen said, 'I never heard of them.' And so, in other (E: well) words, Kefauver's in a quandary as to--

E: What you just said about Sonosky's reaction--and Cohen's reaction--tends to support what I'm saying. That we--this was not an agreement, although Jerry did twist and turn a bit.

M: Yes. Of course everybody in--the point is--

E: I didn't twist or turn. No.

M: The point is, there's great confusion as to where HEW stands on these amendments. And East--

E: I don't think we were ever officially committed as a department on anything at that stage, other than our original report on the bill and the President's letter to Eastland.

M: Well, Eastland seemed to think so. And Eastland said on the floor, 'I have talked to high officials in HEW.'

E: Well, he probably had.

M: And they say that they support--

E: Well, he didn't talk to me on that, and he evidently didn't mean me.

Kefauver and Eastland apparently got different answers or impressions from the same people.

M: Yes! Right. And this is what Kefauver says--he said, 'I'm being double-dealed. What's going on?'

E: And does Jerry Sonosky now tell you that he did agree to those?

M: He kind of--he's trying to split the difference. What he says is that we could live with it.

E: Well. To say that we could live with it doesn't mean that we agreed to it. We were anxious to get a bill out, because there were things in it that were better than existing law, we thought, not to mention the likelihood of doing better on the House side after Senate passage.

M: So, in other words, it was acceptable.

E: No. That isn't 'in other words'--

M: Well, they accepted it (sigh--smile).

E: --doesn't mean that you agree to it.

M: All right. You don't agree to it, but you'll accept it.

E: What choice do you have to accept something when the committee reports it out? You don't have to accept it. Congress can act without your accepting it.

M: Yes. But you could say flatly in the Committee meeting that meets Monday morning that these are drug company amendments and we do not accept them. We will have (E: Ohhh) nothing to do with them.

E: Well, that would have been stultifying. Some of the things we liked

wholly or partly. We liked the idea of good manufacturing practice requirements. We liked the idea of expanded inspection. Other provisions also were improvements over existing law and might be further improved on the House side. In fact--was it at that meeting?--we got an inspection provision adopted that applied not only to drugs but also to food and cosmetics and devices!

M: Right.

E: And it was only in a subsequent meeting, before this bill was reported out the first time, that Mr. Chumbris sidled up to me and said, 'Is it true?' This was in executive session. 'Is it true that the inspection section covers not only drugs, but food and,' I said, 'Yes, and it should.' And (laughs) at that point he sidled over to Dirksen and whispered in his ear and Dirksen got that set aside.

M: Got that knocked out.

E: Yes, or rather limited to prescription drugs. But if we could have gotten that, it would have been a great thing. But, let me see now, you said something in your thesis about the new-drug provisions.

M: In my thesis, I'm commenting on some of the amendments that came out of the so-called "secret" meeting. "Kefauver's bill would have changed FDA procedure so that no new-drug application could become effective unless and until the FDA had specifically approved it. The Eastland-Dirksen Amendments would have retained the current provision but would have extended the initial waiting period to 90 days." Now you were going to comment on that.

E: Yes. The item that you have just read from your thesis, gives a quite misleading impression. Under pre-existing law, an application, so-called, for new-drug clearance would automatically become "effective," in other words,

cleared for the market, unless within 60 days--which could be extended to as much as 180 days--unless within that period, after opportunity for a hearing--in other words, after a hearing if there was a hearing requested--the Secretary refused to let it become effective. That meant that the period allowed for hearing was included within the time limitation of 60 to 180 days. Now. It's true that the Kefauver bill would have eliminated the time limits entirely and would have eliminated the automatic going-into-effect of a new drug application. But, the changes that were reported to the Senate by the Committee on the first go-around--after what you call the "secret" meeting--did not leave present law in effect so that the hearing period would be included in the time limitation. On the contrary, the time limitation--90 to 180 days under the bill--applied only to the pre-hearing time. If the Secretary didn't approve the NDA within the 90-180 days, he must within that time have issued notice of opportunity for hearing, and that notice must schedule the hearing to commence not later than 30 days after the date of service of the notice. But then there was no time limitation--in that phase of the procedure--at all for how long the hearing should last or when the decision should be made after the hearing.

M: Now. Is this the final version?

E: This is the first go-around.

M: No-no. Is this the final bill?

E: No.

M: This is the first--

E: This is not the final law. There were changes made later (M: right) both in the second report on the bill by the Committee and in Conference. The

second report changed the new-drug provision so that (1) there could be no automatic approval, (2) the Secretary was directed, within 180 days, to approve the application if he found that none of the statutory grounds for denial applied, or to give notice of opportunity for hearing, and (3) if a hearing was requested within 30 days after such notice, the hearing must start within 90 days after the 30 days. There was no specific time limit set for the duration of the hearing or for the decision after hearing, though the hearing was to be conducted on an expedited basis. The House version was the same, except that it required the Secretary's decision after hearing to be made within 90 days after completion of the hearing. The conference version and final law resolved this single difference between the House-passed and Senate-passed versions by providing that the Secretary's decision after hearing must be issued within 90 days after the date fixed by him for filing final briefs (rather than 90 days after completion of the hearing). So, first of all, the final law, and earlier versions, did not put any time limit on the time it takes to hold a hearing. It could go on for many months. Secondly, under the final version, the only time limit on a decision is that when the Secretary finally states, 'well, here, I want final briefs by this and this date. I'm giving you a time limit now.' Then he has 90 days after he gets the final briefs--or after expiration of the time limit for final briefs--in which to make a decision. And, incidentally, even then, if he fails to do it, it wouldn't automatically go into effect under this version.

M: Yes. I understand that under the final version, (E: yeah) ah--

E: Well, that's what you asked for--before--

M: Right. But I was--I was--right, I was trying to--

E: But under the first go-around version--

M: Right--first go-around version--

E: But this is--incidentally, this final version that became law is different from the one that passed the Senate. This was worked out in conference. I remember (M: yes) being called into conference to discuss this.

M: Yes. I guess (E: but I can tell you what passed--yes?) what I'm trying to do is trace the progression--this--

E: Well, I can tell you what passed the Senate--what finally was reported out--if that's what you want to know. On the Senate side.

M: Well, I ah--

E: But let me assure you that after that initial thing which you call the "secret" meeting, there was no time limit on the hearing at all. Or on the decision after hearing. In the latter respect it was more liberal than some versions that followed it. Now there was still no open thing so that the application could become automatically effective, if the Secretary, within the time limit, gave notice of opportunity for hearing. If he did nothing within the time limit, neither turning the application down nor giving notice of opportunity for hearing, yes, then the NDA would have become effective automatically under that version.

M: What I implied was that the committee passed the drug companies' version. The drug companies' version--(E: well, it probably did) does allow for automatic--um--approval.

E: If the first committee version is the industry version, you are right about that, but only in the limited way I have stated. Once notice of hearing opportunity was given, that would no longer be true. That would still have been a very important advance over prior laws. But how do you

know that that's the companies' version?

M: Because--

E: That is the proposal of the Pharmaceutical Manufacturers Association?

M: Because--uh--Hruska put the--put those 12 amendments in the Congressional Record. I may be--

E: Do we have that here?

M: I may be misreading the Congressional Record.

E: Well, what--umm.

BREAK

M: Okay. Go ahead. Pick up with that, if you like.

E: Well, to go back to when we reported back to the Department, I think I mentioned that Mr. Goodrich, particularly, and I think the head of the Food and Drug Administration with him, felt that the good manufacturing practice proposal of the Pharmaceutical Manufacturers Association was unsatisfactory--unacceptable--insofar as it provided for regulations of the Secretary merely of an interpretive character and that the Department and the Food and Drug Administration would be better off without any reference to regulations in that paragraph at all. Secondly, the Food and Drug Administration and Mr. Goodrich were very dissatisfied with a provision that would allow only for a requirement of substantial evidence, undefined at that point, of effectiveness of a new drug. And--uh--I do not remember exactly, but--uh--I think it was felt that efforts should be made to get further modification of both of these provisions. As to the effectiveness provision, I remember discussing that with the lawyer for the Pharmaceutical Manufacturers Association, Mr.

Lloyd Cutler, at the so-called "secret" meeting but I do not recall or believe that we ever agreed to it. It was simply one of those things that --uh--this is as much as we could get, and it would certainly be better than what we had--the existing law.

M: Do you--do you recall what it was that--that you could get?

E: We could, at that stage, get no more than the provision that was reported out. That there needed to be 'substantial evidence (including substantial clinical evidence), supported by investigations' of qualified experts, that the drug would have the effect that it purported to have as determined by its labelling and so forth.

M: I have--I have a sentence here and it may be nonsense--'Secondly, the amendments eliminated the term "efficacy" from the definition of a new drug.' (E: Ohhh) 'This deletion meant that if a new use were claimed for an old, established drug, it did not have to be proven efficacious in its new role.'

E: Oh yes. I remember that that was done--that is, that, as at first reported out by the Committee, the bill failed to add references to efficacy to the new-drug definition--but I don't think that we ever agreed to that.

M: But that--but that is essentially an accurate description of what that meant?

E: Well, the initial Kefauver bill, S. 1552 as introduced, as well as in anything that we ever drafted--that I ever drafted--to amend the Food and Drug Act with respect to efficacy of new drugs, including the provisions of HR11581, provided for amending not only the substantive new-drug clearance provisions of the Food and Drug Act to add efficacy, that is, section 505,

but also section 201(p), defining the term 'new drug'. And I just feel morally certain--though I do not remember exactly what was said--that we would surely not have said or implied that failure to amend the definition by adding references to efficacy would be acceptable to us. Of course, if it had been enacted that way, the Department would have operated with it. It would have amounted to a partial grandfather clause. Now the meaning or effect attributed by Kefauver to the Committee's action in deleting that from the bill, which is also the meaning you have attributed to it, was in my view incorrect, for under then existing law, as well understood, such a change in label claims would have required a supplemental new-drug application, at which point, as correctly stated in the first Senate committee report on the bill (page 17), the new use of the drug would have required, under the bill, a showing of substantial evidence of effectiveness as well as proof of safety. But so long as there was no change of label claims, the drug could stay on the market.

M: Maybe this is a good point for you--if you can--to give a definition of what a "new drug" is.

E: Well, the--the Act itself defines the term "new drug" in section 201(p). At that time it didn't have a provision excluding the separately defined term "new animal drug"--but that's not relevant here. And it says: 'The term "new drug" means (1) any drug--and I'm skipping the recent reference to new animal drugs--'any drug, the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in its labeling.' I'm not reading exactly the words and I'm skipping a grandfather clause for pre-1938 drugs. And (2) it's also a new drug--uh--

if 'the composition of it is such that the drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized--that is, among experts--'but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.' Now, the references to effectiveness that I have quoted just now were not in the definition before the Drug Amendments of 1962. However, both in the Kefauver bill as introduced and in anything that we had ever proposed or drafted, and also in the final 1962 law, as it became law, that definition was proposed to be amended so that in each place where there had been only a reference to safety there was inserted a reference to effectiveness. Incidentally, we did accept one thing--we used the term "efficacy" but industry feared that that had the connotation of some general efficacy rather than effectiveness to do the job that was claimed for a particular drug. So we accepted the use of the term "effectiveness" rather than "efficacy." That's one thing we did accept. It didn't make any difference.

M: Let me read to you what I've tried--what I've written in a footnote to try to explain what a "new drug" is--

E: Yeah. I shouldn't have read the definition. I should have done it in my own words.

M: Well, that's what I have attempted to do after reading this. 'Technically, a "new drug" is any prescription drug cleared for the market--'

E: May I interrupt?

M: Please do.

E: You're mistaken about limiting it to prescription drugs. An over-the-counter drug can be a "new drug."

M: Yes. Okay.

E: Go ahead.

M: 'Any prescription drug cleared for the market under the "new drug" application procedure set up by the 1938 Food, Drug, and Cosmetic Act. But evidently, in practice, the definition of a "new drug" is not that clear. Obviously, many "new drugs" are over 20 years old. The Bureau of Medicine wanted to include virtually all prescription drugs, both pre-1938 and post-1938.' Well, this gets us off--

E: Anyway, I don't think you're right in your description of what a "new drug" is. You've--you've sort of turned--put the tail of the dog first. You've said, in effect, that technically, a "new drug" is any drug that is cleared for the market under the "new drug" provisions of the Act.

M: --from 1938 on--

E: But, no. To find out what needs to be cleared for the market, you must first determine what a "new drug" is, and for that purpose you look for the definition, rather than the other way around. So, technically, before 1962, a "new drug" was one that, at a given time, (1) wasn't generally recognized among experts as safe for its proposed use or (2) was a drug that, although generally recognized as safe on the basis of investigational use, hadn't really been used to a material extent or for a material time other than in such investigational use. So under those circumstances, leaving out the pre-1938 drugs now--under those circumstances such a drug could not be put on the market--as distinguished from investigational use for which an exception can be made--unless it went through the clearance procedure for safety. And under the amendments, as finally enacted in '62, a drug that has ceased to be "new" so far as safety is concerned may still, under the

amended definition, be "new" because there is no general recognition, by experts, of its effectiveness for its proposed use, or because that recognition exists on the basis of scientific investigations but the drug hasn't been used for a material time or to a material extent.

M: Now, does this apply to drugs before 1962?

E: Before 1962! In the initial go-around on the Kefauver bill--as distinguished from what we drafted on the House side--H.R. 11581 where we had a transitional provision--there was no transitional provision as such, a glaring defect of the original bill. Under the original Kefauver bill, in the absence of anything else, not only would all the thousands of previously cleared "new" drugs have to go back through the new-drug clearance procedure for efficacy, but they could not legally stay on the market pending such clearance, even if there was no label change. That's poor draftsmanship, for it surely was not intended. On the other hand, under the original committee action, which included no transitional provision either, a worthless drug cleared before 1962 for safety could stay on the market forever if there was no change in label claim, unless the Government, in a court action, carried the burden of proving misbranding. It's true that, if the labeling was changed and say, something was cleared for safety as a new drug back before '62 for treating arthritis, and the manufacturer now claims that not only is it good for arthritis, but it's also effective for gout, it would have to go through the new procedure and at that time even without a change in the new-drug definition. I think that Kefauver was mistaken in his contrary view. But I think we will get into the transitional provisions at greater length, because that was a hot-and-heavy thing.

M: Later on--

E: Later on. But anyway do you want to hear more about this? I don't think so. No.

M: No. I think that's enough information.

E: All right.

M: Well, do you have any other comments you want to make on the HEW response to--

E: Oh, well, umm. Some of us in the Department--I for one and I think Mr. Willcox also--felt that we had gone really too far in insisting on what I might call a straight requirement of effectiveness. I felt that some intermediate ground might be reasonable. The Food and Drug Administration was sort of taking the view, under our version--as distinguished from any version based on a substantial evidence concept--not only would the application have to show effectiveness, there would have to be clear and convincing proof that the drug was effective. And I might say, I don't know whether it was on that occasion but I think we were in some difficulty on that. You see, we were pressing for a stronger effectiveness requirement than a simple "substantial evidence" one. We had been in an executive session and we were going to another one. Jerry had asked Mr. Harvey, who was then Deputy Commissioner of Food and Drugs--and I don't remember whether it was then the first or second go-around--to go to the executive session with us. Jerry, I think, was taking him along, as well as me, to be available if some technical questions came up. In the taxi Mr. Harvey said to Jerry, 'Let me help you on effectiveness--'

M: This was John Harvey?

E: John Harvey. Now, I think that our view would have been to de-emphasize

the strength of our proposal. We would have the feeling that--we had a perfectly reasonable proposal that called for effectiveness but that didn't mean necessarily that if there were two views as to effectiveness of a drug, two respectable schools of thought, with expert evidence on both sides, we would then necessarily turn down the drug. But, as Harvey had said, 'Well, let me help you on that.' Jerry then asked Eastland, I think, to call on Harvey at the executive session, which Eastland did, or maybe Jerry did for Eastland, to ask how the FDA would apply the efficacy concept. Harvey got up, and the first thing he said was that under an efficacy requirement the FDA would require that the evidence be 'clear and convincing.' I inwardly gasped, because this was sure to boomerang. So far as I know, Jerry never said a word about it to Harvey afterward. But now I don't know whether that came up at the earlier go-around or the later one.

M: It might be the later one, I think. I'm not sure though.

E: I think not, because on the later one we really worked--hammered it out with Blair's full participation.

M: That's true. That's true.

E: You see, I might say that the Food and Drug people on the Senate side were not generally used in these negotiations, except the--well, I think Dr. Kelsey was called in and I don't think I was even present at that one, at which she was asked about thalidomide and so forth. And I remember that episode with Harvey, and then Larrick came up with us and this was primarily, I think, in connection with the antibiotics. And I remember that--rather amusingly--he was asked questions of what--what they used antibiotics on animals for--if they used them--and one Senator asked, 'Do you use them to cleanse the tits of a cow when you milk it?' Larrick said, 'You mean teets--

not tits!' (chuckle) (M: heh-heh-heh--who said that--Larrick?) Yes. Everybody laughed. (M: That's a good story!)

M: So you were present the day after--the Monday after the (E: quote "secret meeting" unquote.)

E: I was present at that session--it--I was over on the side in back of the room--that room was--it's too small for anybody but the members sitting around the table--but we were there. Jerry was sitting or standing--or probably mostly standing--next to Eastland and Kefauver was sitting close to Eastland's end of the table on the side--Eastland sat at the head of the table. And when the--these things were sprung on Kefauver he was taken aback--he was taken by surprise. You know. And--uh--as the meeting went on, one thing being approved after the other, Senator Carroll, of Colorado, I think, when the noon hour struck, raised a point of order because the Committee hadn't gotten permission to meet while the Senate was meeting. This ended that executive session.

M: Right. Um--I'm still trying to get clear what HEW's attitude toward these amendments was.

E: Well, you have interviewed Sonosky and Cohen, and they can best tell you, if they still remember, what HEW's attitude was. Jerry, of course, was at the Committee meeting at which the amendments were decided on. He couldn't cross Eastland very well at that meeting. I think that his--uh--his attitude may well have been that 'this is the best we can get' and, as he says, that 'we can live with it.' I--well, for one thing, I just don't believe that he ever agreed--and I certainly didn't--to having a definition of "new drugs" devoid of any reference to efficacy--or effectiveness. As to "substantial evidence," I think he felt that that's the best we could

do at that stage. This was before the thalidomide episode broke. Objectively considered, some of the amendments to the FD&C Act--such as those on factory inspection, new drugs, and antibiotic certification--would have marked a considerable advance over the then existing law, despite some glaring defects in the bill, including some defects stemming from the original Kefauver bill. And--uh--that's it. Now on the--I've forgotten now. It may be that what I mentioned about Goodrich's objections to certain provisions and so forth didn't come until--that he wasn't apprised--this happened over a weekend, so very likely the Food and Drug people didn't even know about that at that point. Uh--I was a little surprised that Jerry didn't draw the Food and Drug people in more on that--

M: Who did? He--?

E: Sonosky. (M: Sonosky.) Yeah. He always brought me in so far as I know--at least on anything that involved drafting--except on any private discussions he may have had with Cohen, Feldman, Eastland, and Blair.

M: Are you going into why--he has an interesting story to tell as to why--say, Rankin, didn't come to the so-called "secret" meeting.

E: He wasn't asked, I think--was he?

M: He--he was asked, but he declined to come.

E: Oh.

M: And Sonosky seemed to think that--uh--he knew to stay away--

E: Uh--heh (chuckle)

M: In other words, that--that some compromising was going to go on maybe--

E: Why, did he say he didn't want to come?

M: Uh--he--he didn't say. That is, Rankin didn't say, but Sonosky said that he did say--

E: If he didn't say--if he gave no reason--I think that would have been an improper thing for him to do--to just say 'I don't want to come.'

M: Yeah. But--but--uh--but Sonosky just replied that Rankin--uh--knew to stay away. (chuckle) Well, whatever--um. Ah, events following the "secret" meeting--uh--sorry, I have to keep using that term, but we're stuck with it. It's too dramatic to do away with! (E: Laughs--hard!) Finally--uh--it seems to me that there is some confusion--certainly in Kefauver's mind and I think maybe generally, as to what the Department's attitude is toward--

E: Well, let me tell you another thing--on the antibiotics--we wanted the antibiotic certification to be--to extend not only as to all antibiotics but as to all antibiotics whether they were used for man or animal. And this is a matter on which I remember talking with Senator Eastland--I think it may have been on the Saturday preceding the Committee's executive session--over the telephone--or maybe it was later--I've forgotten that--uh--he was not there then. He was at his home, I think, and I was trying to give him reasons why I thought we should have that even for veterinary antibiotics. But at any rate--uh--I don't think we would ever have agreed to limit it to--uh--those for general use, but we might have, I don't know. It finally came out that--but, you know, in the second phase, the Senate Committee finally did extend it to all. It was only in the House that--but then the Conference prevailed on limiting the extension to antibiotics for humans.

M: Yes, what--what--what do you see as the next--next significant point in the progression?

E: Well, apart from--well, the next significant point, of course, apart from this episode of Kefauver is the thalidomide episode. (M: Right.) And I don't know who sparked it into fire. It may have been Jerry Sonosky; it may have been Wilbur Cohen or something, and--uh--this was an occasion which might never come again--the possibility of turning this thing around sufficiently for us to get some of the things that we couldn't get in the first go-around. And it was at that point--uh--that this was taken up with the White House, evidently, to which I was not privy, undoubtedly with the President, too, and eventually it was decided that the President would send up a series of amendments

M: And also the President, by this time, has clearly said, 'We do not accept the first version of S1552.' And Ribicoff says that too.

E: Well--I think it was said--yeah--I don't know that--uh--this--you mean at the press conference or something?

M: Well--I--Ribicoff made the statement before--(E: Oh, on the House side)--on the House side.

E: He was unhappy or something with--yes.

M: He was asked and he made it very clear that--

E: I bet that didn't make Eastland very happy. (M: No. No.) But anyway, it was then that we worked into the night on two succeeding nights--it must have been Wednesday--no, it must have been Thursday and Friday--we were in Sonosky's office--Rankin was present until about '9 in the evening the first day, I think. What we were working on at that time, I think, was primarily the explanations, you know. And I was working on drafting legislative language and I looked over the explanations, you know--and--uh--we worked until--the first night, as I say, Mr. Rankin, I think, went home about

9 o'clock. And then Jerry and I worked until very late, perhaps 3 a.m., I don't remember for sure now. He may have gone home before. What does he say on that?

M: Uh--I didn't really ask him on that. We didn't really--

E: So the next--we were not through that night--and the next night I alone stayed after hours. He went home at about 6 or something. I stayed until at least 1 a.m. or something--I don't recall exactly now--until the girls had all the material to type--it was a matter of copying by then--and they undertook to do that and to deliver it to the White House staff in the early morning, before dawn. Two or three times I think, during the night I called Jerry at his home to be sure that he and I were en rapport--in accord on certain points. I don't remember what they were. I did this because I was all alone except for secretarial help, and this was going to the White House. There (M: chuckle) would be no further chance to change it. And that was then delivered that morning, in the wee hours, by one of the girls, to the White House. And--the covering letter may have already been signed--no, I think not--I think it was probably flown to Hyannisport--oh, wait--maybe it had already been signed. Maybe I'm thinking about the first letter.

M: I believe it was the second letter--

E: It was the second letter that was flown--?

M: Harris has a fairly good description of that.

E: That it was flown to Hyannisport? (M: I believe so.) Well, maybe so. But anyway, it was delivered, I think, then--still the next day, I think--to Eastland--and wasn't that a Saturday?

M: I--I'm hazy on--

E: The date of the President's letter was August 3rd. Now, I can check the date on that, if you like--in a calendar.

M: No. I--I can check that.

E: Is that the Harris book?

M: Yeah.

E: The Real Voice?

M: The Real Voice.

E: It's out in paperback? (M: um-hum) Maybe I ought to get it sometime and read it, but I don't think I was--

M: This was a special consumer--uh--Consumer Reports put it out.

E: Consumer's Union?

M: Consumer's Union. I don't remember--

E: I belong to that, but--

M: You might still be able to order it--they'd probably send it--

E: I should not add to his royalties for having done what he did, should I?

M: (chuckle)

BREAK

E: I don't know whether I said this on the tape, but--uh--on the second night--uh--Mr. Sonosky was not present. He had gone home and I was there alone with a couple of girls to work with me--uh--in continuing the drafting of the material for the President to transmit to the Committee--uh. During

the course of the evening, I did speak with--I did call Mr. Sonosky at home two or three times to be sure that we were in accord on certain policy points--that they were properly reflected in the material because there would be no further opportunity for him to review it. I left at something like maybe 1:30 in the morning--I'm not sure anymore--and the girls stayed on to finish the typing--and they were delivering it to the White House later on. I don't think I had said this on the tape before. And it was presumably delivered that next morning on Saturday. The President's letter dated August 3rd was--that was a Friday, and I don't--well--it may--I think it probably was flown to Hyannisport for him to sign and then flown back. But at any rate, on Saturday morning, I think, that material was either in the Senator's hands or I had a copy which I took up to the Committee Counsel, Mr. Tom Collins, I think--whether it was discussed to some extent, I have no clear recollection of it but I have a recollection of being up there that Saturday morning.

M: What instructions--had the instruction come from the White House?

E: Which instructions?

M: To write these new amendments.

E: Well, they didn't come to me directly, nor do I know whether they were initiated by the White House, but certainly there had been an arrangement between the White House and the Department for the President to send up new amendments to the Committee--taking advantage of the impetus that would be given to this course by the thalidomide episode. (M: Mmmmm) And, as you may recall, the President, in his letter to Senator Eastland, starts out saying, 'Pursuant to our discussion, I am enclosing drafts of amendments essential to strengthen S. 1552,' et cetera. So the President either in

person, or on the telephone, must have talked with Senator Eastland on these.

M: What were your instructions to--to--

E: Well, do you mean about drafting--our draft?

M: Right.

E: I should put in one reservation. Looking over these "Presidential" amendments to refresh my recollection, I noticed that there are seven numbered amendments--one of them encompasses several subamendments. And I noticed that one of these is amendment number 6, on advertising. I noticed two things about that. One, it follows verbatim, I think, an amendment on the very same subject that was in a series of amendments to be offered by Senator Kefauver--intended to be proposed by Senator Kefauver--to S. 1552. That amendment, No. 6 in the President's letter, was not drafted by me and I suspect--I do not recollect exactly now--but I suspect that Mr. Sonosky included that under an agreement or arrangement with the Senator--Senator Kefauver--or with Dr. Blair, his assistant--his professional assistant, and I assume, at the urging of Dr. Blair. You will remember that the President, in his Consumer Message, had recommended, among other things, an amendment to the Federal Trade Commission Act in relation to drug advertising. When the Food and Drug Act was enacted in 1938, in the same year when that bill was pending, there was also pending legislation to amend the Federal Trade Commission Act with respect to food, drugs, and cosmetics among other things, that is particularly on advertising those articles. It was called the Wheeler-Lea Amendment (Yes) and that included a provision on advertising of drugs to the medical profession--which was not a very strong--it was a weak provision. Even weak as it was, the Federal Trade Commission had, I think, done very little about it.

M: No case had ever been presented as far as I understand.

E: I see. So, at any rate, Dingell in 1962, or the previous Congress, introduced legislation--whether it was at the urging of the Commission or what, I don't know--to strengthen those provisions of the Federal Trade Commission Act so as to require that advertising of drugs--maybe it was only prescription drugs, I've forgotten--would have to disclose the quantity of ingredients, I think--or maybe that wasn't included--but anyway, the adverse effects, warnings, and so forth--and we endorsed that at that time, I think, already. And in his Consumer Message in 1962 the President recommended its enactment with an added provision about efficacy, I think, which hadn't been in the earlier version. And in drafting our legislation for H.R. 11581, I included that FTC Act amendment and the Department supported it. I think Blair must have encouraged Jerry to go along the route of including the advertising amendment in the Food and Drug Act rather than the FTC Act. It did not eventually come out this way, incidentally, not exactly in policy or draftsmanship. On the Senate side, I worked it over, among others. The final version definitely overrides the Federal Trade Commission Act provision--

M: So the--

E: The final version.

M: So the Wheeler-Lea Act has been superseded in that regard.

E: To that extent and in that regard. And this expressly--whereas, the Kefauver version enclosed with the President's letter, at best would have created a duplicate--parallel jurisdiction.

M: The way it's drafted--

E: There was a big fight in 1938--a big discussion as to whether the advertising of food, drugs, devices, and cosmetics should come under the

Food, Drug, and Cosmetic Act that was then being enacted. Or whether it should be under the Federal Trade Commission Act. And you know what the decision was--so this, in effect, was a reversal to that extent, of that 1938 congressional decision. (M: right) And I think it's obvious from a letter that Rand Dixon, who was then Chairman of the Commission (M: Um-hum) and at one time had been with Senator Kefauver's subcommittee, was unhappy about that, and I can understand why. He wrote a letter to Congressman Dingell, you know, pointing that out and saying that it should be under their Act and that thus it would be more effective than under the Food and Drug Act. And Dingell then asked the Secretary 'what about it,' and a response was prepared but never sent. And I think that someone had talked with Congressman Dingell and, apparently, Congressman Dingell decided not to press for that explanation.

M: Well, evidently, somebody must have gotten to Dixon, too, because I remember going through the written records. Dixon makes the complaint and then you never hear anything else about it.

E: Well. After the President sent that amendment to the Hill, it would have been rather difficult for the Commission, even though it's supposedly an independent regulatory agency, to take issue with that--it seems to me. And it's very interesting how the language--the covering language for that amendment in the transmittal of the President, reads. It's clear that the other amendments, which I had drafted, are proposed by the President. This one (ruffles papers) says, 'We are in complete support of the attached amendment to S1552.' and so on. Now isn't that an odd way of stating that he is proposing it? 'We are in complete support of it.' Well. But anyway, (ruffles papers) so I find that this is the one "Presidential" amendment that I'm fairly sure has language that never came from me. I wouldn't even

refer to a trade or brand name. I would speak of a nonproprietary name.

(M: mm-hmm) And--uh--anyway, there are other deficiencies in that language, you know. But--uh--there it is! (chuckle)

M: Heh-heh.

E: Now--so that's that. And I don't know how soon this was, but things moved rather quickly from that point on. And I suppose--through Eastland further meetings were arranged--I think there were several. And some of them went on for hours and hours, and--uh--at some of the meetings--whether it was more than one I don't remember--but at one I remember Wilbur Cohen and Katzenbach were both present and active, as were the lawyers for the Pharmaceutical Manufacturers Association, that is, Lloyd Cutler and Marshall Hornblower--and I don't recall whether Foley was there or not. If he was, he didn't enter into the discussions. Also present were Senate staff--that is, Tom Collins, Chumbris, and Raitt. We met in a fairly large room--I've forgotten whether it was Eastland's office, but he wasn't there during negotiations, if memory serves me. The negotiations were clearly, really, between the Pharmaceutical Manufacturers Association lawyers--Lloyd Cutler, who was the leading one, and Hornblower on one side and our party on the other side. And, Katzenbach evidently was there to help us. But he seemed to have a kind of mediatory role on occasion. And there were at least two occasions--maybe more--when there was an impasse and he went into an adjoining room with Cutler--and maybe Cutler and Hornblower--to thrash things out and then came back with a joint proposal, you know. In other words, he was trying to be a--what do you call it--a--

M: A go-between?

E: A go-between.

M: "Mediator," I guess, is as good a word as any.

E: But I think--uh--still, on our side. (M: um-hmm) And one of the big issues--there were two big issues and some subsidiary ones, you know. And I think of the ones, certainly, when Wilbur Cohen and Katzenbach were both present, one was on the question of transitional provisions on new-drug efficacy and the question, particularly, whether there should be any kind of true grandfather clause. Uh--and let me--I have found here the--uh--copies of some drafts that were used in or emerged from these negotiations. There were two aspects--transitional provisions for drugs that had at some time been subject to the new drug requirements, and then what to do about those post-1938, mostly proprietary, drugs that had never been considered "new drugs" and thus never subject to the new-drug procedures. Leaving aside, for the moment, those proprietary drugs, what was worked out was an agreement as to those drugs that had, at one time at least, been considered new drugs and been subject to the new-drug procedure and were still on the market. Whether or not they were still "new" drugs didn't matter. It was agreed that those drugs were not to become subject to the amendments requiring premarket initial clearance as to efficacy except with respect to any changed uses, or conditions of use, recommended in the labeling, so long as approval of the application was not withdrawn or suspended under the withdrawal provisions of the Act. Additionally, the new withdrawal provision on efficacy--as distinguished from initial clearance--would not apply to drugs that were already on the market and had gone through the new-drug procedures until two years had elapsed from the date of the enactment of the bill, unless approval was sooner withdrawn or suspended on other grounds.

M: The withdrawal provisions would not come into effect until two years?

E: That's right, generally. You see, this efficacy thing has two aspects.

One,--and also the amendment of the definition of "new drugs"--it has two aspects--first, there's an application filed to get approval of a new-drug application. At that point, safety and efficacy have to be shown. Well, at a later stage, after approval, we might then find, on the basis of the old and new evidence, that, as of that time, there no longer is substantial evidence of effectiveness. In that event, we would withdraw approval under section 505(e)(3) of the Act, the withdrawal provision. And the agreement was that that provision would not generally take effect for two years with respect to drugs already on the market, whether or not they were still "new drugs" at the time of enactment of the bill, but that after the two-year moratorium we could initiate--as to all those drugs on the market that I have referred to--proceedings to withdraw approval on the ground that there was no substantial evidence of efficacy. You see?

M: Certainly. In other words, after two years, drugs that had already been through the NDA process would then have to prove efficacy.

E: They wouldn't unless we started something--(M: uh-huh). Or unless they started something (M: Oh) by asking for (M: Oh) amendment of the new-drug application. Well, since that time--you may have been reading in the papers or in recent Supreme Court decisions about it--the Food and Drug Administration retained the National Research Council of the National Academy of Sciences to create expert panels to review by class the efficacy of each drug approved before 1962 (M: uh-huh)--prescription or over-the-counter--and then come up with reports. Justice Douglas' opinion says that FDA has reviewed the reports of these panels and on January 23, 1968, announced its policy of applying their findings to all drugs, including related me-too drugs. As to some, the reports found no evidence of efficacy, as to some that they were probably not efficacious, and so forth. You see. (M: um-hum)

M: Oh--oh, so old drugs could come under the efficacy rule--after two years.

E: Yes--if they were already on the market and had once been subject to new-drug clearance or, as recently decided by the Supreme Court, were me-too drugs. (M: uh-huh) There was no duty--we couldn't--let's say--two years had passed--we had done nothing and they--the manufacturer--had done nothing but continue to market the thing (M: right). We could not, at that point, say, 'Well, you don't have an approved new drug because we have never cleared it for efficacy.' We couldn't do that.

M: Then are you saying the FDA has--has really--uh--

E: But we--we would have to say we now propose to withdraw approval on the ground that there is not substantial evidence of efficacy--after 2 years from the date of enactment of the 1962 Amendments. It's now over 11 years.

M: Oh.

E: And--we--there would have to be a lack of proof of substantial evidence of effectiveness. The burden of proof would be on the manufacturer.

M: Oh. Oh. So, in effect, then, after two years the FDA--

E: Oh--they would have some new evidence, maybe. Yeah. So--yes--that's what's been going on, you see.

M: In other words, this bill--

E: There would be an opportunity for hearing at that stage, except that the Supreme Court has upheld the validity of FDA's procedure whereby it will not provide a formal hearing when it is apparent at the threshold that the manufacturer has not tendered any evidence that on its face meets the statutory standard of substantial evidence of effectiveness as particularized

by FDA regulations. So much for the transitional provision. Now, of course, any applications for new-drug clearance filed after or pending on the date of enactment, October 10, 1962, would have to be cleared right from the start.

Now, let's go to the grandfather clause. There were, apparently, a lot of drugs, primarily proprietary drugs, over-the-counter drugs, that had never been considered "new drugs." The chief lobbyist for them was a representative of the Proprietary Association, a Mr. Cope(?), I think, a very nice fellow who eventually became its president. And they wanted a complete grandfather clause as to those OTC drugs that had never been subject to the new-drug procedure, even though they were not pre-1938. In other words, apparently their view must have been--and apparently the Food and Drug Administration must have agreed--that there were post-1938 drugs that, at the time they came on the market, were just combinations of old established ingredients universally recognized as safe and hence had never been subject to the new-drug procedure. And they took the adamant position that for those drugs there must be a complete grandfather clause--so long as they don't change their labeling claims. You see. And Mr. Cohen, and Katzenbach with him, of course, were just as adamant the other way. And so, while there was a compromise with industry as to the other drugs, there was none on that OTC class. I have here a penciled mark-up of my first draft which we submitted to the industry people. In that draft, the fourth paragraph--relating to those proprietaries--still was transitional. It provided that the efficacy amendments to the new-drug definition would not apply to drugs already on the market that were not, and never had been, new drugs under the old law, until the expiration of the two-year period beginning with the enactment date or, if later, until the Secretary would make an order (after opportunity for hearing) declaring the drug to be a new drug, subject to

judicial review, of course. Of course, this would not have applied to a change in labeling claims. It says here, in pencil, 'T.E.'s first draft of transitional provision for Section 8 of S1552--penciled changes suggested by "other side." Now the reference to the "other side" was probably to Lloyd Cutler or Marshall Hornblower, I suspect the latter. And he marked it up that way and it was put in clean draft showing, by underscored inserts, the changes that they suggested in my draft. My penciled note shows that the "clean draft" wasn't a perfect composite print of the two versions, but it is nearly so--and, really, they, that is Cutler and Hornblower, hadn't made any substantive change in what I had drafted. But the Committee converted my draft paragraph into a grandfather clause by deleting its transitional language.

M: Wasn't it a real--wasn't it a real coup to get the--the patent medicines under this blanket--even at all? In fact, I--I wasn't aware of that--the patent medicines, too, come under this efficacy rule--or do they?

E: They do now--if they--if any new ones come on the market or if they make new label claims, or if at any time after 1962 and after 1938 they were new drugs or me-too drugs. From what I have read in the press, the FDA is raising the efficacy question with regard to whole categories. But, you see, our draft would have opened the efficacy question even for those post-1938 OTC's that were on the market before 1962 and were never in the new-drug (or me-too) category. On that the Proprietary Association prevailed in Congress, although Cohen and Katzenbach never yielded on it. The Pharmaceutical Manufacturers Association--a number of whose members also made proprietary drugs--would have accepted our proposals, with the few drafting changes I have mentioned, even as to the proprietary drugs. I was told, how reliably I don't know, that Cope--under--under the pressure that kept building up and

considering public relations, was recommending to his own people to go along but they turned him down. So he had to insist on a complete grandfather clause on those proprietary drugs now covered by paragraph (4). As I have said, we did not go along with that and this was never an agreement as to that particular paragraph, paragraph (4). But the committee--the full--the Executive Session--and we were present (loud chuckle)--they went along with the proprietaries on that.

M: So they did get the full grandfather clause.

E: Yes. Yes, for the drugs falling under paragraph (4).

M: And that makes them different from the ethical drugs, does it not?

E: Well, I think--while it doesn't speak of ethical or non-ethical or prescription drugs or non-, my understanding is that either all or most of those drugs that fall within this complete grandfather clause are proprietary drugs--not prescription drugs.

M: So, whereas the efficacy clause can be used to catch ethical drugs before 1962, it cannot be used to catch patent medicines before 1962.

E: Well, it can, under two circumstances. One, if it's a new thing of theirs that comes--that they want to put on the market and subject it to the new drug procedure fully. Also, if they want to change their labeling claims--they claim that it's good for something else now, you know, they would have to come under it because--uh (M: the patent medicine)--yeah. And thirdly, if the drug was ever subject to the new-drug procedure or was a me-too drug. I keep referring to "me-toos" because of the recent clarifying Supreme Court decisions.

M: But as I--as I understand what you're telling me, ethical drugs before

effective for its proposed use, coupled with actual use to a material extent or for a material time other than merely in scientific investigation. This is the curious thing and I don't like it myself. I mean, I think that the law should be far broader. You see, incidentally, the new-drug provisions of the law were not in the bill that was before Congress in 1938, as part of the Food and Drug Amendments. What happened when the food and drug bill was pending in Congress--there was the Elixir Sulfanilamide episode and new legislation was introduced--independent of the then existing Food and Drugs Act and independent of the proposed FD&C Act--to require premarket clearance of new drugs. But eventually, somebody suggested--'Well, it ought to be part of this bill.' And so it was put into the bill that was to become the Federal Food, Drug, and Cosmetic Act before it was passed by Congress. And, it's because of this historical accident I would say, that it really--the way it was drafted doesn't quite fit into the pattern of the rest of the Food and Drug Act. If it had been drafted originally, it would have said that a new drug--defining it--that hasn't cleared through this procedure shall be deemed to be adulterated. And then all the other provisions would have fallen into place. But it didn't say that. It just prohibited the shipment of such a drug in interstate commerce unless certain requirements were met. And the different provisions of the bill had to be amended to fit into this, you see. When we drafted amendments for cosmetics and therapeutic devices for pre-market clearance, we didn't follow that "new drug" pattern--we followed the general pattern I have mentioned as the proper one. So, a "new drug," under the pre-1962 definition, was one--leaving aside the pre-1938 ones--that either was not generally recognized, among scientific experts, as safe under the conditions of use recommended or suggested in its labeling--or that, even though it has become so recognized as the result of investigation, hasn't been in actual use under those conditions for a material period of time, except in investigational

use--in other words, in research--experimental use. The 1962 amendments to the definition added a reference to effectiveness each time safety is referred to in the definition.

M: Yes. It seems like a very broad definition on the one hand--

E: Well, it is broad. It is broad at the beginning, but not after a drug has been on the market for a while. Assume that it's gone through the new drug procedure after 1962, right? It's been cleared. Say 10 years pass or 15 years pass, and now it is generally recognized among experts as safe and it certainly has been in use for a substantial period of time other than merely in investigational use. So it's no longer a new drug. And that means that none of the provisions of the new-drug safeguards, for instance the requirement for reports about adverse experience, can any longer apply to that drug. Moreover, it seems to me that a drug universally regarded as safe, and thus no longer a "new drug" may be found to be unsafe later and thus again be a "new drug." It doesn't make any sense, does it? A drug can be a new drug for a long time because I think the FDA has taken the position--and I think the courts have probably sustained it--that if there's a disagreement, let's say between the scientists of the Department and other scientists--in other words, a difference of opinion, then, it's not generally recognized among experts as safe. Now this same provision now applies to efficacy, you see, so far as the definition is concerned. So it isn't as wide open as one might think, yet there are no objective criteria that one can point to as to when a drug ceases to be a "new drug."

M: And that's why it's so difficult to grasp what a new drug is--

E: If you want to find out whether something is still a new drug, I think, the only safe thing is to ask the Food and Drug Administration. So there have

been instances where the manufacturer says to the FDA, 'Well, I think it's no longer a new drug. My drug, therefore, is not subject to premarket clearance. If you don't agree, sue me.' It's screwy, y'know. And until recently the Government might have the burden of showing de novo in court that the criteria of the new-drug definition are met. However, the Food and Drug Administration under the more recent position they've taken, and this has been sustained by the Supreme Court, can by a declaratory order decide whether a drug is a "new drug," subject to direct judicial review on the record. Also, in a proceeding on a new-drug application (NDA), the FDA has jurisdiction to adjudicate the status of the drug as a "new drug." The first alternative at least is something novel. It used to be thought that if the drug manufacturer did take a defiant stand, the Government would actually have to go to court and get an injunction or other remedy on the ground that the drug is a new drug and hasn't gone through the new-drug procedure, and that would be a de novo proceeding and the court might find otherwise--or a jury, even. So now, with these decisions, I think the FDA is in a much better position.

M: So a new drug is virtually what the FDA says it is.

E: Subject to an opportunity for a hearing at the administrative level and judicial review and so forth. But it's an amazing thing--. So, this is an extremely important and interesting aspect, but--so this, coupled with the transitional provisions of the 1962 Amendments, has led to thousands of drugs being reviewed for efficacy and gradually, more and more, they're getting into the over-the-counter drugs, also. They must be ones that have been new drugs, I think, or me-too drugs.

M: I mean--I mean, that would be abs--unbelievable! If efficacy was really applied to patent drugs. (E: Well, I think it--) Holy smokes! Can you imagine--!

E: Well, it certainly does to new ones.

M: To new ones--since '62?

E: Oh, no question--

M: No question about that--

E: Just as in the case of safety. Except for the pre-'38 ones where they never changed the labeling claim.

M: I know. But can you imagine if the legislation was attempted before 1962 to prove efficacy of patent drugs. I bet they would fight that just tooth and nail!

E: Before '62--? Even a pre-1962 (post-1938) proprietary drug that had been a "new drug" at any time before the 1962 amendments or a me-too drug, would be only under the transitional provisions and not the grandfather clause.

M: Before '62--huh!

E: Yes. Well, somehow or other, I think that Kefauver didn't realize the implications and ramifications of this subject to start with. In general, he had tried to limit his bill to prescription drugs because his hearings--investigations--were related only to that. (M: Right.) But that provision was not thus limited and so--

M: As I said before, I think it's amazing that you got any coverage of patent medicine at all. (E: Yes. But why not call them over-the-counter drugs (OTC)? The term "patent medicine" may have a connotation of quackery.)

E: Well, we also got in a "good manufacturing" provision that's not limited to prescription drugs.

M: That's interesting.

E: Now. Another important thing that came up--shall I go on?

M: Go ahead.

E: This is a copy of--I think that's the kind of paper used on the Hill. (ruffles paper) It bears a penciled note that says "Factory Inspection." And it says here in my handwriting, 'Agreed to in principle between Cohen, Katzenbach, and other side.'

M: Uh-huh.

E: It looks like nothing here, but it's important. There were two things. One, was on the question of how far, if at all, HEW--Food and Drug--should be able to concern itself with the qualifications of personnel in drug factories--in drug manufacturing establishments. Now, initially, in our draft of the good manufacturing practice provision, which you will notice in H.R. 11581, we had specifically referred to personnel as well as controls and so forth. In our factory inspection draft, while not expressly mentioning personnel qualifications, the language was broad enough to cover them. The PMA lawyers were adamant and at first succeeded on not mentioning personnel in the good manufacturing practice provision. And, as you may recall, they also succeeded in having personnel data expressly excluded from the first reported version of the Senate bill, the Kefauver bill, of the broadened factory inspection provision with respect to prescription drugs. So on this there was hard bargaining. I think this may have been one of the occasions, in the post-thalidomide phase, when Katzenbach went into another office with the industry people and returned with a compromise to which Cohen agreed. The compromise in principle was to qualify the exclusion of personnel data in

the factory inspection provision by permitting inspection of 'data as to qualifications of technical and professional personnel performing functions subject to regulation under this act.' (I later deleted the reference to regulation in perfecting the draft.) So the idea was, although not expressed the way I would have preferred to express it--I don't like the 'performing' phrase--was that there we could look at the personnel qualification data relating to technical and professional personnel. At the same time--this doesn't appear in the paper I'm looking at--in the good manufacturing practice paragraph, although not referring expressly to personnel, after saying that a drug would be deemed adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packaging, or holding, did not conform to current good manufacturing practice, there was inserted a phrase that would also deem a drug adulterated if those methods, etc., were not 'operated or administered in conformity with' current good manufacturing practice. That phrase was intended to encompass personnel, key technical and professional personnel, and this is so stated in the report on the House version of the bill. The House Committee embraced this provision in that respect. So that was one hard fought worked out compromise, with Katzenbach and Cohen being in on that and being instrumental on that.

Another one on factory inspection was on the same paper bearing my notation about agreement in principle between Katzenbach/Cohen and the "other side." Research data were among the things that had been excluded from the factory inspection scope for prescription drugs in the first version that was reported out of the Senate Committee--any data relating to research. And it was agreed as noted on that paper, that that would be changed to read 'research data (other than data subject to reporting and inspection under the [new-drug provisions or antibiotics provisions] of the Act).' And I think, at my urging, that limitation on the exemption of research data was enlarged a bit even, so

as to cover also other drug data that would have been subject to reporting and inspection under the new-drug section if the drugs involved were new drugs. It's a little complicated.

Those were very important matters. I've already covered the very important transitional provisions on new-drug efficacy. Now, let's see whether there were other things in the factory inspection provisions that we worked out.

M: Were any of the Kefauver people involved at this stage of the game?

E: Yes. You see, in all this second phase, Kefauver's man, Blair, was present. And cooperating, collaborating, as pleased as can be (M: heh)--and this --this is all that was needed to--. And when you look--read the debates and how complimentary Kefauver was about all the cooperation--and so forth. Some of the things he would have criticized before were all right now, you see.

M: Hmmm. Well, what do you think made the--made the change?

E: The fact that he was being brought into the thing--he wasn't excluded from having his own bill under negotiation.

M: Hmm. So but obviously they must have been in a more conciliatory mood--

(E: Well of course!)--Kefauver and Blair.

E: But yes.

M: Yeah. I wonder--

E: I think if this had been done in the first instance it might have resulted in a quite different history. I'm not sure it would have ended up better. But for thalidomide it probably would not have.

M: I think Sonosky suggests that Blair and, well mostly Blair, finally began to realize that you people weren't the enemy.

E: Oh! I think this is very true. Very true. (M: yeah)

E: In connection with the matters that we negotiated in the second phase in Senator Eastland's office--not in his presence but in the presence of the Committee staff, including Dr. Blair and including staff for Senator Dirksen and Senator Hruska--with our people on the one side and the industry, the Pharmaceutical Manufacturers Association, on the other, a subject of negotiation was the definition of substantial evidence of effectiveness.

I have not, have I?

M: You touched on it. But maybe you need to--

E: Well maybe I ought to mention this first. Um--if it's all right to cross that with the other?

M: Sure.

E: I don't recall who came out with the first draft of the definition. Well, let's see. There was an industry draft (ruffles papers) on effectiveness that we rejected. The industry draft was, I think, a counterdraft to one by Blair that I'll mention presently. In lieu of a definition, the industry draft would have required refusal of new-drug clearance if 'there is a lack of substantial evidence that, in adequate and well-controlled clinical investigations, experts qualified by scientific training and experience to evaluate the effectiveness of such drug, have fairly and responsibly concluded that the drug will have the effect it purports or is represented to have under the

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E: And I had told you about after this blow-up, how nice he was to me.

(M: yeah) Even though I was ashamed to have lost my temper.

M: Was this about the time of the blow-up? Was the blow-up in the second phase of the--

E: Even later. The blow-up was in the morning of the day on which the conference between House and Senate was to start--was the conference to start at 10 in the morning or at 1 in the afternoon?--I've forgotten. But we were to meet--I think at 9 or 10 in the morning--we were to meet around the table--we, I mean our people and--uh--not the Food and Drug Administration people--they, I think, were not present--Jerry Sonosky, I think, was--but, I'm not even sure of that--but I was there certainly. And the Senate staff people, including Dr. Blair, and the lawyers for the Pharmaceutical Manufacturers Association. I suppose Ed Foley must have been sitting there, too. And we went over different things trying to reconcile them--to try to arrive at last-minute--see what we could agree to that was still not in agreement. And--uh--and I wanted to bring up something in relation to the nomenclature provisions, the standardization of drugs. This was on a Monday, I think. The previous day, Sunday, I had talked with Marshall Hornblower on the phone because they had a version of the nomenclature provisions and I wanted to try to point out some of the drafting bugs in that. And he and I came to an agreement on that--over the phone--and the understanding was that the next day they would have it typed--I would have it--and gotten to the conference. But at the Monday meeting I couldn't get a word in edgewise--Blair kept on talking. And he was talking about something that had already been resolved. If he'd only let me mention my point--and finally, as I say, I blew up and shouted at the top of my voice, 'Will you listen to me!' (M: chuckle) And

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this is when a hush fell over the room and--uh--everybody was--I think--embarrassed. I was. And I started getting a heart--my angina pectoris heart seizure. So I--subsided, too. But I also apologized and said that--uh--not that I was wrong--I was only wrong in losing my temper. But he was just as gentle and nice to me--not only on that occasion after that moment, but in the future, and in any subsequent dealings I had with him before that thing became law and maybe afterwards. Very pleasant.

M: That's a great story.

E: Pardon?

M: That's a great story.

E: It's true. I was--as I say, I was ashamed, and still am, because I don't like to lose my temper.

END OF CLOSED PARAGRAPHS

conditions of use prescribed, recommended or suggested in the proposed labeling thereof.' Well, we rejected this particular version, and I think the primary reason was that it didn't really define what substantial evidence was but rather what it was to be about. All it called for was substantial evidence that experts had reached these conclusions fairly and responsibly. Still, this isn't far from the version that we finally came up with, but I think the other--the version we finally came up with in the give and take of discussion is somewhat better although, if I were drafting it today, I think I could perhaps much improve on it. But I do remember, for its interest to you--one thing how this came up exactly. It came up in these negotiations--and I think even Wilbur Cohen and Katzenbach may have been present at that moment--but they may not have been--I don't remember. But Dr. Blair--John Blair--came up with a version in which he proposed something close to the definition we now have. And I remember that he particularly had in there a requirement of well-controlled--he said they must be well-controlled--investigations. In fact, as I have said, I think that the industry draft I have just read from was probably in response to what Blair had come up with. But, anyway, I remember saying that it was fine to require well-controlled investigations but they might still not be adequate. And I suggested adding a requirement that the investigations be adequate. Blair seized on this--'Yes, we must have adequate and well-controlled investigations!' This is how it evolved. So, as I said, I believe that the Blair draft we were discussing, but amended to include the requirement of adequacy as I had suggested, then preceded the industry draft because the latter has both of those concepts in it. And there was considerable discussion back and forth and that was a very important part of the discussion--and part of the give and take in these negotiations on what was meant by substantial evidence of effectiveness. And that's considered in the recent Supreme Court decisions because the Food and

Drug Administration has issued regulations as to what is called for. And the validity of those regulations has been sustained.

Incidentally, it was agreed that, contrary to the Committee's earlier decision, the definition of a new drug should also be amended to include the concept of effectiveness.

But coming back now to the--we were negotiating the grounds for withdrawal of approval of a new drug. And, as you will recall, in the earlier-reported version of the bill, in the provisions on withdrawal of approval, the Committee had put in the efficacy matter, and they had put in a provision that approval could be withdrawn also if the labeling of the drug was false or misleading in any particular. We had gotten that into the grounds for denying approval in the first instance, so it was put into the withdrawal grounds as a counterpart. And also the old provision for withdrawing approval if the new-drug application contained an untrue statement of material fact. Now, we proposed in the amendments submitted by the President with his letter of August 3rd, we wanted to get certain additional grounds for withdrawing approval. These included, as stated in the President's Amendment No. 4, any failure to maintain records and make reports if required by the Secretary under authority of another provision in the bill, and any failure to maintain required quality manufacturing controls. And this was the subject of considerable discussion at these meetings. Also included was an amendment to suspend approval pending a hearing to withdraw approval, if the Secretary found that there was an imminent hazard to the public health. So the industry lawyers submitted a long counterdraft, dated August 16th, for additional grounds for withdrawal of approval, or for suspension before a hearing. Well, this was not quite satisfactory. In part it went in a direction that seemed reasonable to me, in seeking to mitigate the unqualified harshness of our draft of additional withdrawal grounds. For instance, suppose that the

labeling of the drug were false and misleading in some particular. Under our draft we could then withdraw approval of the new drug. That would mean putting the man out of business--just on that one thing--if that were the only drug, at least--out of business for that drug. On the other hand, the industry went too far the other way. With respect to any or all additional withdrawal grounds, it would have permitted withdrawal action by the Secretary only if the act or omission involved (a) was willful or grossly negligent and created a substantial hazard to public health, or (b) was not corrected within a reasonable time. We insisted on differentiating between the different types of violation involved and appropriately adjusting the withdrawal sanction to each. Industry agreed. The compromise is the present wording of the second sentence of section 505(e) of the Act. To reach full agreement on those provisions there were perhaps hours of discussion and much give and take on the particular provisions. That negotiation I had with their lawyers--maybe Jerry was in on this, but I doubt that Cohen and Katzenbach were even there at that point. I'm not sure. But what was eventually hammered out was acceptable and fair, I think, to both sides. I have a "clean" industry draft of the next day, August 17, that we discussed and on which I noted a couple final suggestions.

The industry's counterdraft also included provision for summary suspension of approval of an NDA if the Secretary found an imminent hazard to the public health, but it was so hedged about with procedural qualifications as to be unacceptable. The Committee eventually gave the Secretary the authority we wanted, but it was made nondelegable at Senator Eastland's insistence.

Incidentally I remember that on the Sunday that was, I think, the day before the Monday conference we were still working on--Marshall Hornblower

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E: I--heh--I (small chuckle) was a little amused by one thing. I don't recall the exact detail, but I know it was on this--Lloyd Cutler had slipped up on something and he thought he was catching me on something. I was proposing something which I thought was helpful to them, you know, and he cut in sharply, and I said, 'Well, if you want to have it your way that's all right with me.' So (chuckle) the people with him nudged him (both chuckle)--he was caught on that as a matter of fact! I think he was somewhat embarrassed there.

M: In other words, he was advocating something the--

E: Yes. I was really being fair, I felt, and suggesting something on their side.

END OF CLOSED PARAGRAPH

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and I, in that Committee office--fixing drafts up for the conference. And I remember he asked me to draft certain provisions, just leaving it to me, trusting me. In other words, there was built up, between him and me, a degree of mutual trust, reliance on each other's professional integrity. And in fact, it was on that Sunday afternoon, I think, that I then called him, trying to get agreement to change the standardization-of-names provision, and I explained it and he agreed that it was technically much better my way than the version then in the bill. And he said, 'Well, let's have it typed tomorrow morning and sent over to the Conference Committee and then we'd get it there!' But the next morning, because of delay caused by Blair at a meeting preceding the Senate-House Conference, I could not get it done in time. We were standing outside the conference room, and it wasn't coming and I was fretting, and when eventually it arrived, the copies were still all wet--I don't know what kind of duplicating process was used--and there wasn't any possibility of getting the matter corrected anymore. So I think this is why we have a provision in the law now that isn't as good as it would have been--as simple as what we could have had on standardization of names.

On factory inspection--here's an August 16th draft--this was after earlier discussions--I have here on top, 'Agreed to by Mr. Cohen' and I have 'OK-T.E.' here. This is the provision, I think I already mentioned, that modifies the earlier escape hatches from the factory inspection authority that had been in the earlier version of the bill. It now would permit us to look at qualifications of technical and professional personnel performing functions subject to the Act, and would permit us to look at research data relating to new drugs and antibiotic drugs that are subject to the record and reporting requirements authorized under other parts of the bill, and other drugs that, if they had been new drugs, would be subject to the same requirements. So that this was agreed to, I see, by Cohen. It might be of

interest. And we agreed that, in order to preclude any roll-back of any existing authority that might arguably flow from a reverse inference from the additional inspection authority we were getting, there should be a sentence to prevent that. So, I just have a note here, 'No roll back.' And that was added, you know, in--in good language. And also, another thing that I had put into our bill on the House side, and that was agreed to here and put into effect, was to authorize courts to issue an injunction if a person refused us admission to inspect the premises. Under pre-existing law, the only sanction in such a case was criminal prosecution. There was an express provision in existing law prohibiting an injunction in such cases. With the amendment we could, by civil judicial command, get in there without having to put a man through criminal prosecution, without having to go to criminal court and maybe--and maybe not, get an indictment. Why the limitation was put into the original Act I don't know.

END OF REEL II - SIDE 4

START REEL III - SIDE 1

E: Here is an interesting thing. Remember, we had some--I had had some discussion about the prescription drug advertising provisions to go into the bill, and the fact that the President had transmitted, as his amendment number 6 with his August 3rd letter, a version that had come from a Kefauver draft and that I had not drafted, and that the accompanying explanation referred to it as a provision that 'we fully support,' rather than saying 'this is our proposal.' Well, I have here a draft revision of that proposal which, I gather, was handed to us by Senator Eastland's staff. (M: Right.) And I marked that up, I see, with pencil notations all over it to change, partly to perfect the draft language and partly to make substantive changes. For example, I cut out the provision that the Secretary's regulations could not require his

prior approval of the particular text of any advertisement. I don't recall whether I made that last change on my own initiative--perhaps as a matter of legal interpretation--or otherwise. At any rate, my revision was then put in clean draft which I have here--with my interlineations underscored. The proviso I had deleted is simply omitted from that revised draft. But anyway, I have a note on top of the clean draft that says, 'T.E.'s revision of Eastland's revision of President's proposal to Eastland.' And this is very nearly what finally went into the law, although there was some give and take between the House and Senate in Conference on this later on, the most important change being adoption of a House proviso limiting to extraordinary circumstances the Secretary's authority to require prepublication approval of advertisements by him. But an important thing is--unlike the Kefauver version that the President sent to Eastland--that this actually overrode, expressly, the provisions on drug advertising in the Federal Trade Commission Act under the Wheeler-Lea Amendment, except that I got that modified to say that the FTC Act was overridden only in respect to the matters specified in this new amendment to the Food and Drug Act or covered by regulations of ours under it. And that went into the final version. In my revision, I added another paragraph, a saving clause for proceedings that might already have been pending or instituted under the Federal Trade Commission Act. But that was eliminated. There probably weren't any such proceedings anyway.

I have no clear recollection about negotiations with industry lawyers about extending the certification requirements of the law for certain antibiotics to all antibiotics. For veterinary antibiotics, we lost on the first try, won on the second go-around, lost in Conference. And that reminds me, at an executive session of the Committee during the second period, they had Mr. Larrick up there, among others you know. He was in the room, in executive session, on the question of the antibiotic drugs. And there were two suggestions

that he personally, speaking for the Food and Drug people, made at that time. One was that even though we might have granted an exemption from the requirement of certification of batches for a particular antibiotic, if a manufacturer nevertheless wanted to obtain certification of a batch or batches of the drug--if he applied for and met the requirements for certification, that should be permitted. And secondly, that, contrary to a provision that was in the bill as originally reported out, nothing in the Act should be deemed to prevent the manufacturer or distributor of an antibiotic from making a truthful statement in labeling or advertising of the product as to whether it had been certified or exempted from the requirement of certification. The purpose of both of these provisions was to somewhat protect small manufacturers who couldn't, on equal terms, financially and economically, compete with the big people. And if a small man, although his product was among those exempted by the Secretary from the requirement of batch certification, wanted certification of his product in order to be able to market it advantageously, he should be permitted to get the certification and to say so on labeling and in advertising. And these changes were accepted by the Committee and they asked for language for it. So, I said to Larrick, 'Well, you go ahead and give them the language on that one,' because I didn't know exactly what he wanted--it wasn't as clearly expressed in his oral statement as I thought I needed--so FDA supplied that. That was language actually prepared and submitted by the Food and Drug people--sent to the Committee. It may have been cleared with me, but I didn't draft it.

Now, this takes us through the executive sessions in the second go-around. Then they reported the bill out, you know. Incidentally, I worked considerably with Tom Collins in getting things prepared for the Committee, because he had no background in this field since these matters were not within that committee's subject-matter jurisdiction. And he invited me to work with him on the Committee

report. Meanwhile, Sonosky was sitting with the industry people. I don't remember what they were working over. And, when the industry people saw that I was to work with Tom Collins--I worked with him at night on that--they were a little disturbed, I think. And--well, I did two things. One was, I called Wilbur Cohen on the telephone. By that time Sonosky was back there, I think. I may already have mentioned this--what was happening--I told Wilbur that I'd been asked to do this but that I couldn't serve two masters. And I said 'Will you relieve me or release me from any obligation to represent you when I'm working with Tom Collins on the Committee report?' And he said, 'Yes--go ahead.' (laughs) (M: chuckle) And I had a little difficult time because I was sitting there with Tom at night, and I had, for instance, written out something that was sound, I thought, but I said, 'No, I think you'd better not say this.' Because I was looking at it from the standpoint of his Chairman and his role in relation also to the industry and Dirksen, Hruska, and so forth. So I was trying to be very fair from that standpoint.

E: Now. Here I have several--I've made myself Xerox copies--several changes proposed on various things in the bill. These were, I think, submitted by industry--they're all dated August 28th, after S.1552 had been passed by the Senate and while H.R. 11581, together with the Senate-passed bill, was still under consideration in executive session in the House committee. You will note that the two-page summary of the 8/28/62 proposals refers only to S.1552, while the 13-page elaboration was addressed to both the House and Senate versions and might have been prepared to influence House committee action as well as preparatory to Senate-House conference, I don't know.

BREAK

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E: Now, I might mention to you that, when the bill was about to go to the Floor--the second version of the bill--a speech was to be prepared for Eastland, and I think, in the first place, Tom Collins had been asked by Eastland to do this, and Jerry Sonosky had offered (chuckle), 'Let me help--' or 'Let me work on it.' You know. I don't know whether I heard Jerry say this at the time, but I learned that the next morning at least--or that night, I believe. So we met again the next morning with Tom--about 9 in the morning or something like that--or before--and Jerry said he had sat up until 3 in the morning to write that speech. Did he say anything to you? (M: No.) And--uh--so we--we were about to start on it--going over it, what Jerry Sonosky had prepared, when suddenly a call came from the Chairman's office--the Chairman wanted to see Tom Collins. So Tom went in and came back with a document--sort of crestfallen--and said--uh--'This is the speech that the Chairman told me to look over--this is the speech!' And what he had said to Tom was, 'See if there are any bugs in it.' Well, now, it seems to me a fair inference that Eastland didn't write it. I think it is also a fair inference that Staff didn't write it. And, finally, I think, it is a fair inference that the industry representatives--the Pharmaceutical Manufacturer's Association's lawyers--had written it. We looked it over; read it over. It was a fine job--beautifully written, really very capably written--and there were only one or two places where we found some bugs in it. It was not the way Jerry and I would have wanted to see it written, but, really, it was a masterful job, I felt. And I think we all recognized this!

M: And, do you feel it was slanted towards the drug industry's point of view?

E: Well. Of course it's a long time--I haven't (M: yeah) recently refreshed my recollection on that. I only remember how well-impressed I was as to the

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capability of the person who had written it. It wasn't something that was so flagrant and open that we could tear it to pieces as something obviously distorting and so forth. You see.

M: But--but you certainly think that it was written by the--uh--by Cutler or--Hornblower or--

E: Or their--their speech writers--but probably Cutler (M: yeah) or something because it was a masterful job, I thought.

M: That's interesting. --And then this was the speech that Dir--uh--Eastland used to introduce the bill?

E: Oh, yes. --Not to introduce the bill--it was already pending on the calendar--but to take it up for debate.

M: That's interesting.

END OF CLOSED PARAGRAPHS

M: Then these were additional--aft--even after the bill had been passed by the Senate on August 23 (E: right)--the drug industry--

E: Yes. One suggestion included was to delete an amendment added to S.1552 on the Senate floor. This was preparatory to House Committee action and/or conference--

M: Now these are changes the drug industry wanted to make.

E: These are changes of the drug industry--at a time when both Senate and House versions were still under active consideration in the House Committee. And I wrote my reactions on the margin of the summary at the time. They were in pencil but this is a Xerox copy of the document that was on file. The Xerox copy didn't come out too well, so I traced in ink the comments I had made in pencil. This summary, you will note, consists of "A.Major" and "B.Minor" proposals. Of the major changes--the first one relates to a Senate floor amendment by Kefauver on animal testing of drugs before testing on humans. When first offered, the amendment was mandatory in form and would have required the Secretary's regulations to require such tests on animals, and approval thereof by the Secretary, and require the investigators of the drug on humans to register with the Secretary, keep records, and send the Secretary copies of their reports. However, before a vote, Kefauver changed his amendment so as to vest in the Secretary discretion on all this. Incidentally, Jerry Sonosky may have been involved in this switch. He had been admitted to the Senate floor at Senator Eastland's request (M: Yes, he told me.) and I remember being amazed at this. Usually the staff of the Committee or personal aides of Senators are admitted, but for others it is a most unusual thing, although I've seen it happen. I saw him conferring down there when I was in the gallery.

M: Wasn't Jacob Javits pushing--pushing for this too? As well, I think.

E: Well, I think he claimed to but this was pretty much--you're talking about the disclosure to the patient?

M: Yes, yes.

E: That's a different one. I'll come to it. That one particularly--and I'll come to--that's an important one. But on this one the industry proposal after Senate passage was to cut out the Kefauver amendment, not because they objected to the part requiring tests on animals and disclosure of the results to the Secretary, but because of the other provisions of the amendment. The corresponding House language did not parallel Kefauver's version except to the extent of specifically authorizing the Secretary to require "preclinical tests" adequate to justify the proposed clinical testing. In conference the House version prevailed, except that Kefauver managed to get "(including tests on animals)" inserted after "preclinical testing." The final language negates any requirement of direct reports by clinical investigators to the Secretary. We had no objections to these changes, especially because the final wording included language that made clear that the Secretary had broad authority to impose additional requirements to protect the public health. The latter language, in Kefauver's amendment, stemmed from something I had drafted. The next "major" industry proposal of August 28 was to modify the proviso authorizing the Secretary to suspend a new-drug approval summarily if he found an imminent hazard to public health. The industry people wanted to amend that proviso to incorporate the substance of the Senate legislative history as to the circumstances when the power of need of suspension could be exercised. As explained by them, what they had in mind was Senator Eastland's floor statement that the power should be exercised only after consulting the manufacturer and, where time permits, after obtaining the advice of an independent panel of scientific and medical experts of the

National Research Council of the National Academy of Sciences. I just put a big 'No.' there. (M: heh-heh-heh-heh) The next proposal was on medical journal advertising--see that paragraph on advertising? They wanted to modify clause (3) so as to substitute a mere requirement that the advertisement contain a conspicuous notice referring the physician to the manufacturer's literature for full information as to side effects, contra-indications, and effectiveness. In the alternative, if the clause (3) were retained, they would add a proviso 'forbidding prior FDA censorship of language of each advertisement.' And I have a big 'No' on both of those.

M: Of course this is--was the so-called Younger amendment in the House that had been defeated. (E: Uhh--) The essence. I guess they're still attempting to get that (E: Well--) back in.

E: However, the final House version, which prevailed in conference, did require clause (3) information only in brief summary, and did bar a prepublication approval requirement 'except in extraordinary circumstances.' Now--next, on extension of antibiotic batch certification. They wanted to strike that, though they gave a wrong citation. They did succeed in excluding veterinary antibiotics, as in the House version. Next item--time for acting on new drug application. Their proposal was to modify the bill on new-drug clearance so as to require an opportunity for conference during each 60-day period of the initial 180-day period for approving the application. On that I have a big 'No' with an exclamation mark. And that they didn't get. They also wanted to require that, in the event of a hearing, the decision would have to be issued within 60 days after the close of the hearing. On that I noted 'Absolutely not!' They did get the '90 days after the date fixed for final briefs.'

M: Now, were you actually meeting with the drug people at--?

E: Well I was meeting with Jerry at least. Now whether, at the moment that I made those notes, I met with anyone else I don't remember--or whether I gave those to Jerry or not--I don't know anymore. But I do know this--that I've got this physical evidence (M: right). And I suppose I must have been consulted on it at least. But I--I just can't--we may have been meeting on it though. I just don't remember. Maybe it was given to the Committee staff and they gave us these and we are reacting. Then they have (B) Minor amendments. On the grandfather clause on effectiveness requirement for existing new drugs. They sat 'Strike the present 2-year limitation on the grandfather clause' (turns paper). In other words, make it a real grandfather clause. And on that I just have a 'No.'

M: But that's not exactly a minor amendment, is it?

E: Indeed not! And we had really agreed on that with PMA lawyers in the negotiations on the Senate side with Katzenbach in on it.

M: So, in other words, they--they just were not giving up until the last. (E: Nooo.)

E: See, they took the view--yes, they had agreed to these things in relation to the Senate bill as it went through the Senate, but this did not commit them--they took the view--uh--as to what should happen on the House side or in Conference. Now, next is 'size of type for official names on labels.' They say--amend Section 9(a), subsection 4, so as to eliminate unintended ambiguity as to size of type for official name of an ingredient and size of type for official name of drug in brochures and other labeling in which the brand name appears--frequently in varying sizes. Now there was an amendment on the House side, incidentally, I think it was the O'Brien amendment, which had said something about where it should be--but that was cut out on the floor

by himself. I just have a note on the margin here--'No ambiguity'--because I didn't, at the moment at least, see an ambiguity. Next--uh--on the registration of drug plants. It says 'Amend the section to make clear that registration is required for foreign plants whose drugs enter U.S. commerce.' They had drafted that section--that was, as I told you, an industry proposal--just a minute.

M: What proposal was this?

E: The registration of drug plants. (M: Yes.) This is different (M: Yes.) from--from the licensing (M: the licensing provision) provision that Kefauver had (M: right) changed to refer to registration (M: right) uh--this--

M: In other words, they reneged on their own proposal.

E: Well--well--not reneged--no, but expanded. They wanted to--you see--amend it to provide that registration is required for foreign plants whose drug products enter U.S. commerce. And I have in my marginal notes 'No!' They claimed that this would be a clarification of their proposal. I rejected it on the ground that the State Department would object. I knew what that Department's attitude was. But the provision that thereafter actually went into the bill in conference was that a foreign manufacturer could register--it would be allowed to register. But if such a manufacturer did not register, then we would advise the Secretary of the Treasury to send us samples of every shipment for examination; otherwise the FDA generally only makes spot checks except in specific instances.

Now. The next "minor" item is confidentiality of information disclosed to the Secretary, the suggestion being to add a new provision corresponding to the original version of section 202 of HR 11581. We had a provision, that I regretted later, that I had put in the draft bill that became HR 11581. There

was a confidentiality provision in the Food and Drug Act, section 301(j), which, in effect, makes it a prohibited act to disclose to anyone, except to the Secretary and employees of the Department or in judicial proceedings, information acquired through factory inspection or under certain other sections of the Act, if the information concerned any method or process entitled to protection as a trade secret. I had drafted an amendment that went into the House bill that would have cut out the limitation as to trade secrets on the one hand and inserted a phrase also authorizing, on the other hand, disclosure "as authorized by law." This was intended to reassure industry about the increased factory inspection authority. But I regretted it because I asked myself, 'What if this is construed to prevent us from making public something that we had found and that the public, for its protection, needs to know?' So, I regretted that and preferred having the amendment deleted from the House version. However, when HR 11581 was reported on September 22, it appeared that the Committee had added a proviso--attributable, I believe, to Congressman Moss--that so alarmed industry, I believe, that the whole provision, not merely the proviso, was dropped in conference. The basic provision that I'm talking about was not in the Senate bill--it was in the House bill only. The Moss proviso stated that 'nothing in this Act'--that's the Food and Drug Act--'shall authorize the withholding of information from the duly authorized committees of the Congress.'

(M: uh-huh) Well! From the point of view of industry, that would be something.

M: It would open the door! Heh.

E: And--and they-- It was just dropped in Conference. The whole thing!

(M: Heh-heh-heh-heh.) Instead of trying to refine it. (turns papers) As for the rest of the 13-page industry proposals of August 28, I could lend you this and ask you to return it.

M: Okay. Why don't we do that.

E: This is the--

M: Those are the industry proposals--

E: This is a thirteen-page industry document of the same date--August 28th--.
Now, let me just mention one or two other things.

M: All right.

E: I mentioned to you that we met around a table--I think it was on the very morning of the Senate-House Conference--trying to iron out things. And then they went--we went over to the Capitol--we were outside the Conference Room--Senator Eastland wanted me in there and I'm sure that Tom Collins wanted me there. Tom had told him how helpful I had been to him and Eastland--I remember one time when I was sitting in the Executive Session of his committee next to Eastland and he passed a note to me that looked--on one side was a tally sheet of votes of the Committee--I'm sure I saved it--I have it somewhere but I can't find it now--it said--'Mr. Ellenbogen, I appreciate your assistance' or something like that, you know. It was nice. And he wanted me to sit in on the Conference, at his side, with Tom Collins, and I think he wanted Jerry, too. Well, when the conferees on the part of the House--the managers on the part of the House--marched into the room, uh, Congressman Schenk objected to our presence. He said he thought that only Members and staff should be there--staff of the Committees and Legislative Counsel, you know. And Senator Eastland said, 'Well--uh--we want them.' And so then Schenk said, 'All right, let us on the House side caucus.' And they caucussed and came back, saying they wouldn't sit--they wouldn't confer unless we were put out. So--out we went. Hehheh. And we were sitting or standing in the corridor outside the Conference Room. This was a conference room that's on the East side of the Capitol--that new extension

(M: um-hum). And it's a room--the middle of which is exactly the center between the two Houses, you know, the table--in fact, the center (M: laughs) of the table--is the center between the two Houses! They had that conference room, and so this went on for some hours, interrupted by roll-call votes. In fact, I think it was a two-day affair. They didn't get through in one day and Senator Eastland was there for most of the first day, but then something--terrible things were happening in Mississippi from his standpoint. There was this business about Governor Ross Barnett trying to block the admission of Meredith--was it?--to (M: right) the University of Mississippi--and big headlines (M: riots on the University campus) and poor Eastland--he was greatly upset, I think. Whether you are in accord with his position or not is another question. But he was really upset and I think he got sick or was needed elsewhere, and--anyway, he gave his proxy to Senator Hruska. Dirksen wasn't there, I think. There was Kefauver, you know. But Eastland wanted--I remember on that first day particularly he wanted us in and so--after every recess he was trying to get us in there again--and--he'd say, 'Come in. Sit down!' And then Schenk (he pronounced it Skenk) would come back from a vote and say or gesture "out" or something like that. Heh, heh (laughs).

M: Well, why do you think Schenk didn't want you in there? Was it just a matter of principle or do you think he--

E: It may have been a matter of principle with him. If so, I think it's carrying the separation of powers doctrine to a degree that may not be good from the public interest standpoint. But--

M: Or do you think he was acting in the drug industry's interest and hoping that by keeping (E: That's possible.) you out he could--

E: That's possible. (M: uh-huh) Whatever the reason, I don't know. (M: You

don't know.) But from time to time they'd call Jerry or Rankin or me in-- I was called in only a couple of times, I think, actually called in by the conferees to be questioned on some particular aspect that I might be able to throw light on. One, for instance, was bearing on this question about the timing--of when the Secretary should make the decision on a new-drug application --after briefs are filed and all that. And so, this happened.

Now, I would like--there were a couple of interesting items that you might want down here. For one thing, there was a difference between the two versions --Senate and House--as to this business on the label and labeling of a drug-- on the relationship between the size of the so-called established name, the generic name, of the drug and the size of the proprietary or brand name on the label and labeling. The Senate version required, both on any label and on labeling, that the generic name be printed in type at least half as large as that used for any proprietary name of the drug. (There was a like requirement for the names of ingredients.) The House version, as amended on the House floor, provided that in the case of labeling, this requirement was to apply only to the first place, and to the most conspicuous place if other than the first place, at which the brand name appears. It was thus rather clear and, I think well understood by industry lawyers, that if the Senate version prevailed it would be interpreted--and read--to mean that every time that a brand name of a prescription drug was used either on its label or any labeling the generic name would have to appear each time in at least half that size. And they tried to have the House-passed version retained in conference. I remember Lloyd Cutler brandishing a drug brochure before our eyes and exclaiming: 'Isn't it enough on the front page and once more!'

M: Lloyd Cutler was the one waving the brochure and saying this?

E: I think it was he. He was trying to get us to agree and he presumably

thought if we agreed then everything would be all right. We did not agree. The Senate version was agreed to by the conferees. Later there was litigation on the meaning of the law. The drug industry sued the Department on the ground that the Department was misconstruing it. I didn't follow that and I don't know who won or whether there was a compromise or something.

M: But as far as you understand the intent of the law was that everytime the brand name is used, the generic name was to appear.

E: That was the intent insofar as one can speak of it--the intent of the law in my view and, in the light of the conferees' elimination of the House floor amendment, was certainly the understanding, I think, of those who were involved. It might have been unclear if the House floor amendment, which was an industry amendment, had not been in conference. What the courts said about it later I don't know. But, be that as it may, that's an interesting item.

The other item was this. On the House side there was the Friedel Amendment requiring disclosure to the patient in the case of an investigational new drug--that it is an experimental drug, and requiring the patient's consent. (I had drafted something that intentionally left an escape hatch if in the professional judgment of the investigator disclosure to the patient was not in the best interest of the patient or was not feasible.) By the way, perhaps at this point, before discussing the Friedel amendment, I should mention on that very question the Javits-Carroll amendment which was added while the bill was on the floor of the Senate. Jerry was on the floor at the time and I was in the reception room outside the Senate lobby. Every once in a while somebody would come and show me something--'Is this amendment technically correct?' 'Would you draft something quickly?'--and so forth. In other words, I was standing by for giving technical assistance. Well, suddenly--I think it was Lloyd Cutler or another industry lawyer--came up to me with an amendment which

apparently they were trying to persuade Javits to offer on behalf of himself and Senator Carroll, to offer instead of an amendment that would have required notice to a patient of the experimental character of a new drug. And so the substitute amendment was simply to add a reference to 'interests of patients' after a reference in the bill to the ethics of the medical profession. Remember? As I recall, the industry lawyer showed me the proposed amendment, 'Will not this do it?' or words to that effect. I was aghast. And I said, angrily: 'You know that isn't true!' Let me tell you why I said that. (turns pages) The bill provided for adding language to the FD&C Act authorizing the Secretary to establish by regulation record keeping and reporting requirements, both in the case of new drugs still in investigational use and those already on the market. With respect to drugs in investigational use (so-called IND's) the authority was inserted in the subsection relating to exemption of experimental drugs from premarket clearance. With respect to new drugs already on the market, such authority was put in a new subsection. This was something the Administration had wanted. A proviso had been added by the Committee, at the industry's suggestion originally, that regulations issued under either subsection 'shall have due regard for the professional ethics of the medical profession,' meaning, I suppose, that HEW shouldn't require disclosure of the names of patients in reports to it, 'and shall provide, where the Secretary deems it appropriate, for the examination on request by the person to whom the regulations are applicable of similar information received or otherwise obtained by the Secretary.' The Javits-Carroll amendment, as I have said, inserted the phrase 'and the interests of patients' after the reference to medical ethics. It seems to me that the industry people sold Javits a bill of goods that that would really relate to the same matter as a meaningfully drafted provision on disclosure to, and informed consent by, a patient as to the use of an experimental drug. But this is merely part of a proviso relating

to record keeping and reports to the Secretary.

M: It's--uh--. In fact--it got put in the wrong place.

E: I suppose that the industry lawyers, in proposing it, had no illusions about it. They could argue that, since the proviso referred to "regulations under" the subsection on IND's, the reference included all regulations under that subsection, not merely the regulations on record keeping and reports. But, anyway, despite my reaction, they apparently went back and got Javits to offer it. I don't know whether Jerry Sonosky was involved. Now--it didn't quite help because, in conference, there still was the Friedel amendment in the House version. By the time of the conference Celebrezze was the Secretary. The Friedel amendment required the Secretary to require informed consent of the patient or his representative, but there were proposals to give the Secretary discretion in the matter, as well as otherwise liberalizing the amendment. Celebrezze was all upset because he did not want any discretion that would subject him to pressures from both sides; he wanted to be able to say that he had to do this. He had already, incidentally, issued proposed new regulations under the broad old investigational-use authority, but not on this point, I think. So Jerry Sonosky was charged with seeing to it that any Friedel-type amendment coming out of conference was mandatory, that the Secretary would be able to say, 'I have to do this.' A requirement of informed consent was the matter that industry was very much afraid of.

M: He has to do what?

E: As it came out of conference, finally, the Secretary has to put into the regulations a requirement, as a condition of permitting a drug to be shipped by the manufacturer for investigational use, that disclosure be made by the investigator, to the patient or his representative, of the investigational

nature of the drug and that the consent of the patient or his representative be obtained, (M: So Celebrezze wanted--)except, as stated in the conference version, when in the investigator's professional judgment this would be contrary to the best interests of the patient or when the investigator deems it not feasible.

M: Of course, that's the big loophole.

E: Well, but that kind of exception I argued for, and I drafted one along that line. Billy Goodrich argued against it. It seems to me a very sensitive matter for the federal government to dictate to a physician using an experimental drug what he should tell the patient. It seemed to me that some qualifying words were needed because there were all sorts of possible circumstances where a good doctor might not consider it in the best interests of the patient to tell the patient or where it would not be feasible to do so. This is a debatable subject. (M: Yes, yes, I recognize that.) One need only read the Senate debate leading up to the Javits-Carroll amendment to realize that. So, the exception is a loophole, and how big it really is depends on the conscience and good faith, I think, of the investigator. And, anyway, Celebrezze wanted the word 'shall' rather than 'may' so as to leave him no choice. But I think in conference they were disposed to have 'may,' so Jerry practically got down to--Ron Raitt, I think--on his knees virtually to--as a personal favor to him--try to keep the word 'shall.' Heh (laughs) I thought that was interesting. (M: Yeah.) And the conferees left the Friedel amendment mandatory on the Secretary. This is not to be confused with the 'except' clause that the conferees tacked onto the Friedel amendment, leaving the matter in the final analysis to the professional judgment of the scientific investigator. On another point Kefauver was very adamant on getting his Senate floor amendment for animal testing before testing on humans in there, and there is

something on animal testing, but not, I think, as strong as he had.

I think you probably want to wind up here. I just want to say that--uh-- I remember that after the conference was over, I noticed Rankin going to the telephone--telephoning to his people--and saying--uh--'I think we got a good bill.' Up to that point I wasn't sure what he really thought. (heh-heh-heh-- laughs) I might also mention that, when the bill was in executive session on the House side before being reported to the House, we were standing by and occasionally Rankin would be called in. Once, I think, I was called in. Anyway, I worked--helped a bit there--to the extent that we could. On the House side, I might say, both before and after Senate passage, I would say that the House committee consulted more the Food and Drug people than us--heh (laughs).

M: That's the impression I have.

E: Yes--huh (laughs) (M: right). Except Menger--Jim Menger, since retired, was the professional man on the House Committee--a very brilliant man. Very able, and I had excellent rapport with him. And I did work with him to some extent on this. For example I think it was at his request, to carry out a Conference decision, I redrafted as an amendment to the section on 'prohibited acts' the Senate provision that would have deemed a prescription drug misbranded if the manufacturer did not furnish to practitioners on request correct copies of the required package insert. It made better sense thus. Well, is there anything else?

M: No. Let me thank you for your--uh--(E: Fine.) long hours--very full--

E: I'm afraid I rambled quite a bit--

M: A very full discussion of these provisions.

E: I'm afraid I rambled a lot and omitted many things. My memory is like a

sieve. Perhaps I should have kept a diary, but it never occurred to me that it would ever be all right to go beyond the record.

END OF INTERVIEW WITH T. ELLENBOGEN

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